

# EXHIBIT 7

REDACTED

# EXHIBIT 8

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ABBOTT CARDIOVASCULAR  
SYSTEMS INC. and ABBOTT  
LABORATORIES INC.,

Plaintiffs,

v

MEDTRONIC VASCULAR, INC. and  
MEDTRONIC USA, INC.,

Defendants

)  
)  
) Civil Action No. 98-80 (SLR)  
) (Consolidated with C.A. No. 98-314  
) (SLR) and C.A. No. 98-316 (SLR))  
)  
)

)  
) **REDACTED**  
) **PUBLIC VERSION**  
)

) **JULY 9, 2007**  
)  
)

**DECLARATION OF GARY SCHNEIDERMAN, Ph.D.**

I, Gary Schneiderman, hereby declare as follows:

1. I am a Division Counsel for Abbott Vascular, Inc. I have worked for Abbott Vascular and related or predecessor companies, including Advanced Cardiovascular Systems, Inc. and Guidant Corporation (collectively "ACS"), since 1986 in various capacities relating to the development of devices for interventional cardiology, including Director of Research and Development and Fellow in the Business Development group

2. In April 2000, ACS and Cordis/Johnson & Johnson ("J&J") settled a series of lawsuits involving various products and technologies. In one of the lawsuits, ACS had sued Cordis in the Northern District of California for infringement of its Lau patents. In another of the lawsuits, J&J had sued ACS, claiming that its Multi-Link stents infringed J&J's Palmaz and Schatz patents and that ACS should be permanently enjoined from selling its Multi-Link stents. As part of the parties' settlement agreement, ACS received a license to practice J&J's stent

patents, including the Palmaz and Schatz patents, and ACS granted J&J a license to practice ACS's patents, including the Lau patents

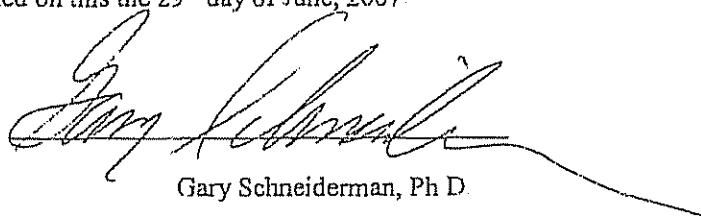
3. In May 2000, ACS and Boston Scientific settled a series of lawsuits involving various products and technologies, including ACS's Multi-Link family of stents. In one of the lawsuits, ACS had sued BSC in the Southern District of Indiana for infringement of its Lau patents. In another of the lawsuits, Boston Scientific had sued ACS, claiming that the rapid-exchange delivery system used with certain models of its Multi-Link stents infringed Boston Scientific's patents and that ACS should be permanently enjoined from selling those Multi-Link products. Under the settlement agreement, ACS received a license to practice Boston Scientific's rapid-exchange patents, and ACS granted Boston Scientific a license to practice ACS's Lau patents

## **REDACTED**

5. ACS has never licensed its Lau patents to an unrelated third party (e.g., a competitor) for money alone. The few licenses ACS has granted to third parties have been purely in the context of securing important settlements and cross-licenses, or in relation to a joint-development agreement.

6. ACS has a general policy against licensing its Lau patents simply for money and has no interest in licensing them to Medtronic or anyone else on that basis.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code. Executed on this the 29<sup>th</sup> day of June, 2007.

A handwritten signature in black ink, appearing to read "Gary Schneiderman", with a long horizontal flourish extending to the right.

Gary Schneiderman, Ph D

# EXHIBIT 9

REDACTED



# EXHIBIT 10

REDACTED

# EXHIBIT 11

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C.

## FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2000

Commission File Number 1-13388

## GUIDANT CORPORATION

(Exact name of registrant as specified in its charter)

INDIANA  
(State or other jurisdiction of  
incorporation or organization)35-1931722  
(IRS Employer  
Identification No.)111 MONUMENT CIRCLE  
29TH FLOOR  
INDIANAPOLIS, INDIANA  
(Address of principal  
executive offices)46204  
(Zip Code)

Registrant's telephone number, including area code: 317-971-2000

## SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT:

<u>TITLE OF EACH CLASS</u>	<u>NAME OF EACH EXCHANGE ON WHICH REGISTERED</u>
Common Stock	New York Stock Exchange Pacific Exchange, Inc.
Preferred Stock Purchase Rights	New York Stock Exchange Pacific Exchange, Inc.

## SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT: None.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months, and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in the definitive proxy or information statement incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

The aggregate market value of voting stock of the registrant held by non-affiliates as of March 12, 2001 (Common Stock) was approximately \$15.2 billion.

The number of shares of Common Stock outstanding as of March 12, 2001:

CLASS	NUMBER OF SHARES OUTSTANDING
Common	308,897,559

Portions of the following documents have been incorporated by reference into this report:

DOCUMENT	PARTS INTO WHICH INCORPORATED
Registrant's Annual Report to Shareholders for fiscal year ended December 31, 2000	Parts I, II and IV
Registrant's Proxy Statement for the Annual Meeting of Shareholders to be held May 21, 2001	Part III

ACS00641205

**Item 3. LEGAL AND REGULATORY PROCEEDINGS**

The Company is currently a party to various legal actions which have occurred in the normal course of its business. The litigation includes disputes over intellectual property, product liability, employment litigation and general commercial matters.

The Company currently has a number of disputes with Boston Scientific Corporation ("BSC") and its subsidiary, SciMed Life Systems, Inc. ("SciMed"). On May 17, 2000, the Company and BSC agreed on a settlement structure covering all patent litigation pending between the two companies. The parties agreed to dismiss all litigation, except the appeals pending in the following lawsuits:

- A. The lawsuit filed on August 12, 1998, by ACS and Guidant Sales Corporation ("GSC") against SciMed and BSC in the Southern District of Indiana alleging that SciMed's NIR stent infringes certain patents. In the lawsuit ACS is seeking injunctive relief and monetary damages. On June 28, 2000, the court granted BSC's and SciMed's motion for summary judgment of non-infringement and entered a final judgment dismissing the case. The Company has appealed this decision.
- B. The lawsuit originally filed on May 31, 1994 by SciMed against ACS in the Northern District of California alleging that the ACS RX ECLIPSE Coronary Dilatation Catheter infringes certain patents of SciMed. SciMed subsequently amended the complaint to allege infringement by the ACS RX MULTI-LINK Coronary Stent System. SciMed appealed the court's order granting ACS' motion for summary judgment of non-infringement. On March 14, 2001, the United States Court of Appeals for the Federal Circuit affirmed the decision of the District Court granting ACS' motion for summary judgment of non-infringement.

The Company currently has a number of disputes with Medtronic, Inc. ("Medtronic"), and its subsidiary Medtronic AVE, including the following:

- A. On October 10, 1995, ACS filed suit against Medtronic in the Northern District of California alleging that the Medtronic FALCON coronary dilatation catheter infringes a patent of ACS. In addition, on March 12, 1996, ACS filed a separate lawsuit alleging that the product infringes another patent of ACS. Both lawsuits have been consolidated. On August 25, 1999, the court granted ACS' motions for summary judgment of infringement, validity and enforceability of the patent. A jury trial was held on ACS' claim of willful infringement and damages. On November 3, 1999, the jury returned its verdict finding that Medtronic had willfully infringed the patent and awarded ACS \$5.4 million in damages. The court held a hearing on December 15, 1999 on ACS' requests for injunctive relief, enhanced damages, pre-judgment interest, costs, and to declare the case exceptional and on Medtronic's motion for a new trial. On April 14, 2000, the court granted ACS' request for enhanced damages and denied Medtronic's request for a new trial. Medtronic has appealed this decision.
- B. On November 6, 1997, Medtronic filed a lawsuit against ACS in the United States District Court for Minnesota alleging that the ACS RX MULTI-LINK Coronary Stent infringed a patent owned by Medtronic. Medtronic amended its complaint on August 27, 1998 to add Guidant as a defendant. Trial by jury commenced on October 18, 1999, and in late November 1999, the court granted ACS' and Guidant's motions for a directed verdict of non-infringement. A Final Judgment of non-infringement was then entered on January 12, 2000. Medtronic appealed, and the hearing on the appeal occurred in January 2001. Medtronic filed a second lawsuit on May 17, 1999 to add allegations that the ACS MULTI-LINK RX DUET Coronary Stent System, the ACS MULTI-LINK OTW DUET Coronary Stent System, the ACS MULTI-LINK SOLO Coronary Stent and the ACS MEGALINK Stent infringe the same patent. In this new complaint, as well as the complaint in the earlier action, Medtronic seeks injunctive relief and monetary damages. In view of the appeal of the Final Judgment of non-infringement in the first lawsuit, the parties have agreed to a stay of all actions in the second lawsuit pending the outcome of the appeal.
- C. On December 24, 1997, ACS filed suit against Medtronic AVE in the United States District Court for the Northern District of California alleging infringement of three patents of ACS by certain Medtronic AVE stents. This case was subsequently transferred to the District Court of Delaware. On April 10, 1998, ACS filed another suit against Medtronic AVE alleging infringement of an additional ACS

# EXHIBIT 12



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## Guidant Announces Settlement Structure for Patent Litigation

**Indianapolis, IN — May 17, 2000** — Guidant Corporation (NYSE and PCX: GDT), a world-leader in the treatment of cardiovascular disease, announced today that it has agreed with Boston Scientific Corporation on a comprehensive settlement structure covering all current patent litigation pending between the two companies. The patent disputes involve coronary stent systems and dilatation catheters.

As part of the settlement, the companies have agreed to license certain patents to each other. In addition, the companies have agreed to certain specified financial terms depending upon the ultimate resolution of motions currently pending in Guidant's lawsuit against Boston Scientific in Indiana related to Guidant's stent patents, and in an appeal by Boston Scientific of a lawsuit filed by Boston Scientific against Guidant in the Northern District of California related to Boston Scientific's dilatation catheter and stent delivery system patents. All other disputes between the companies will be immediately dismissed.

"Guidant is pleased to reach this agreement with Boston Scientific," said Ronald W. Dollens, Guidant president and chief executive officer. "We've eliminated the enormous expense and uncertainty that is associated with litigation, while once again taking a leadership position in creating a mutually agreeable situation that ensures that patients will continue to have access to the life-saving technologies at issue in these cases."

A global leader in the medical device industry, Guidant provides innovative, minimally invasive and cost-effective products and services for the treatment of cardiovascular and vascular disease. For more information about Guidant's products and services, visit the company's Web site at <http://www.guidant.com>.

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# EXHIBIT 13



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## **FDA Approves Landmark Treatment for Coronary Artery Disease**

### **Cordis' CYPHER(TM) Sirolimus-eluting Coronary Stent Dramatically Reduces Reblockage of Coronary Arteries**

MIAMI, Apr 24, 2003 /PRNewswire-FirstCall via COMTEX/ --

Cordis Corporation, a Johnson & Johnson company, reported today that it has received approval from the U.S. Food and Drug Administration (FDA) to market its CYPHER(TM) Sirolimus-eluting Coronary Stent, making it the first U.S.-approved combination drug device intended to help reduce restenosis (reblockage) of a treated coronary artery. Restenosis is one of the greatest challenges in long-term patient treatment in interventional cardiology.

"Cordis is very pleased to bring this remarkable and innovative treatment to patients, hospitals and interventional cardiologists," said Johnson & Johnson Company Group Chairman Robert Croce, who has worldwide management responsibility for Cordis Corporation. "Clinical evidence and experience with more than 50,000 patients treated to date in nearly 60 countries, suggests the CYPHER Stent represents the beginning of a new era in interventional cardiology -- an era in which the combination of drugs and devices substantially improves patient outcomes."

Jeffrey W. Moses, M.D., of Lenox Hill Hospital, New York, a principal investigator in the U.S. clinical trials for the new device said: "The CYPHER Stent clinical trials set a new standard in coronary artery stent investigation. No other stent in this category has been studied so extensively in such a wide range of high-risk patients with difficult-to-treat lesions. Clinical evidence is clear that cardiologists can use this new stent with confidence."

Mr. Croce explained that the FDA approved the CYPHER Stent under an expedited review for use in native coronary arteries with reference diameters of 2.5 mm to 3.5 mm and lengths in 8, 13, 18, 23, 28 and 33 mm. This covers the majority of stent cases performed today.

"Our main objective is to make the CYPHER Stent available to all patients in need of this medical technology as quickly as possible," Mr. Croce said.

The CYPHER Stent was first introduced by Cordis in April 2002, and is now available throughout Europe, the Middle East, Canada, Asia-Pacific and Latin America.

#### **Combining Drug and Device for a New Era in Interventional Treatment**

Combined with the pharmaceutical agent sirolimus\*, the CYPHER Stent is placed into a human coronary artery to prevent restenosis (reblocked arteries). Sirolimus, marketed as Rapamune® by Wyeth Pharmaceuticals, is a commercially available drug developed from a naturally occurring substance first isolated from soil samples in Easter Island in the South Pacific.

"Years of research and development involving hundreds of drugs led to our selection of sirolimus for the CYPHER Stent," Mr. Croce said. "Our collaboration with Wyeth resulted in this significant medical advancement in coronary care, opening the door to future drug-device therapies."

Mr. Croce added, "The clinical benefits of our CYPHER Stent are compelling. We are seeing solid clinical results, out to three years in our initial pilot study. These results will have an increasingly positive impact on patients."

"It's gratifying to see the impact Rapamune (sirolimus) has had in treating patients with coronary artery disease, and its potential for an even broader application in other parts of the vasculature," said Robert R. Ruffolo, Ph.D., President, Wyeth Research. "The use of Rapamune has had a significant impact on the field of transplantation, and now we're seeing its potential to help the hundreds of thousands of patients who receive cardiac stents each year."

#### **Setting a New Standard**

The stent's treatment process, or mechanism of action, is controlled by a polymer coating that gradually releases the drug sirolimus into the vessel lining to prevent scar tissue growth, a

frequent reaction that leads to reblockage following current treatment procedures.

"Reblockage of coronary arteries has remained a stubborn obstacle to successful long-term patient treatment," said Dr. Moses. "Currently, restenosis occurs in as many as 30% of patients who receive a bare metal stent.

"Our goal is to treat a blockage one time, and one time only," Dr. Moses added. "This is our patients' expectation. Now we have a treatment that can significantly reduce the incidence of re-blockage, potentially sparing tens of thousands of patients the need for repeat interventions, including bypass surgery."

The CYPHER Stent is the only drug-eluting coronary artery stent whose performance is supported by two large-scale, randomized, double-blind, controlled clinical trials.

"These trials, involving approximately 1,400 patients, continue to support the long-term unprecedented results for the CYPHER Stent," said Dr. Moses.

Data from the two-year follow-up on the pivotal European RAVEL trial and the one-year follow-up on the landmark U.S. SIRIUS trial were presented at the American College of Cardiology's 52nd Scientific Session in March. The CYPHER Stent data showed sustained reduction in the incidence of re-blockage by more than 90% as compared to a conventional bare metal stent, with a greater than 95% chance that patients can avoid retreatment. The outstanding results were achieved in a broad range of patients, including those with complex lesions and at high risk for reblockage.

#### Public and Private Coverage for Drug-eluting Stents

Recognizing the medical value of drug-eluting stents, the Centers for Medicare and Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services, moved forward in August 2002 with approval of incremental reimbursement for the new medical device, effective April 1, 2003. This new policy provides significant incremental reimbursement over and above the current bare metal stent reimbursement levels. Cordis is also actively engaged with Medicaid and private insurance payers to grant coverage and incremental reimbursement for drug-eluting stents.

A recent independent economic analysis of the SIRIUS trial performed by David J. Cohen, M.D., Harvard Clinical Research Institute, showed that the CYPHER Stent was cost-effective at one-year post treatment and will enable payers to recoup virtually all costs associated with the CYPHER Stent within 12 months. The analysis looked at actual hospital in-patient and outpatient cost data, beginning with the period of initial hospitalization and ending one-year following stent implantation.

For every 100 patients treated with the CYPHER Stent, there were 19 fewer revascularizations and 25 fewer hospital admissions than with the conventional stent, translating into substantial post-treatment healthcare savings. Physicians or patients inquiring about information on the CYPHER Stent can either visit [www.CYPHERUSA.com](http://www.CYPHERUSA.com) or call 1-800-781-0282.

#### About Cordis Corporation

For more than 40 years, Cordis Corporation, a Johnson & Johnson company, has pioneered less-invasive treatments for vascular disease. Technological innovation and a deep understanding of the medical marketplace and the needs of patients have made Cordis the world's leading developer and manufacturer of breakthrough products for interventional medicine, minimally invasive computer-based imaging, and electrophysiology. Today, 5,300 Cordis employees worldwide share a strong commitment to continue the company's groundbreaking work in the fight against vascular disease.

#### About Johnson & Johnson

Johnson & Johnson, with approximately 110,300 employees, is the world's most comprehensive and broadly based manufacturer of health care products, as well as a provider of related services, for the consumer, pharmaceutical, and medical device and diagnostics markets. Johnson & Johnson has more than 200 operating companies in 54 countries around the world, selling products in more than 175 countries.

\* Cordis has entered into an exclusive worldwide license with Wyeth for the localized delivery of sirolimus in certain fields of use, including delivery via vascular stenting. Sirolimus, the active

drug released from the stent, is marketed by Wyeth Pharmaceuticals, a division of Wyeth, under the name Rapamune®. Rapamune is a trademark of Wyeth Pharmaceuticals.

NOTE TO MEDIA: Electronic illustrations and B-roll of the CYPHER Stent are available.

NOTE TO INVESTORS:

Johnson & Johnson will conduct a conference call with financial analysts to discuss the CYPHER Stent approval and launch plans at 12:30 p.m. Eastern Daylight Savings Time on April 24, 2003. A simultaneous webcast of the call for interested investors and others may be accessed by visiting the Johnson & Johnson website at [www.jnj.com](http://www.jnj.com). A replay will be available two hours after the live webcast by visiting [www.jnj.com](http://www.jnj.com) and clicking on "Webcast Archives" in the Investor Relations section.

(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from the Company's expectations and projections. Risks and uncertainties include general industry conditions and competition; economic conditions, such as interest rate and currency exchange rate fluctuations; technological advances and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; domestic and foreign health care reforms and governmental laws and regulations; and trends toward health care cost containment. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99(b) of the Company's Annual Report on Form 10-K for the fiscal year ended December 29, 2002. Copies of this Form 10-K are available online at [www.sec.gov](http://www.sec.gov) or on request from the Company. The Company assumes no obligation to update any forward-looking statements as a result of new information or future events or developments.)

For more information on Johnson & Johnson, please visit the Company's website at <http://www.jnj.com>.

SOURCE Cordis Corporation

Cordis Press - Martin E. Schildhouse, +1-786-313-2545, Cell: +1-305-606-3577, or Terri Mueller, +1-786-313-8687, Cell: +1-305-903-9980; Johnson & Johnson Investor Relations - Helen E. Short, +1-732-524-6491, Stan Panaszewicz, +1-732-524-2524, or Lesley Fishman, +1-732-524-3922; Johnson & Johnson Press Contacts - David Swearingen, +1-732-524-3544, Cell: +1-908-803-6811, or Jeffrey J. Leebaw, +1-732-524-3350, Cell: +1-908-227-7231 /Company News On-Call: <http://www.prnewswire.com/comp/467347.html>

<http://www.jnj.com>

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News Provided by COMTEX

# EXHIBIT 14

**Press Release**[Print Page](#) | [Close Window](#)**Boston Scientific Welcomes New England Journal of Medicine Articles on Drug-Eluting Stents**

NATICK, Mass. Feb. 12 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today welcomed the online release of several important articles scheduled for publication in the March 8th edition of the New England Journal of Medicine (NEJM). These articles confirm the safety and efficacy of the Company's TAXUS(R) Express2(TM) paclitaxel-eluting coronary stent system (TAXUS Stent) when used for the indications included in its approved labeling. The TAXUS Stent was approved by the U.S. Food and Drug Administration (FDA) in March 2004 for use in first-time lesions up to 28 mm in length in coronary vessels between 2.5 and 3.5 mm in diameter.

In total, the findings support Boston Scientific's own internal analyses, publications, physician communications and public presentations of the TAXUS trial data, showing that patients who received the TAXUS Stent for on-label indications had nearly a 50 percent reduction in the need for repeat procedures to treat vessel renarrowing, with no increase (in fact a slight numerical decrease) in the risk of all-cause death or large heart attack, compared to the patients who had received the "control" bare-metal stent (BMS). These findings had previously been verified by independent examination of the data, and are now further confirmed by the additional independent analyses reported by Drs. Mauri et al, and Dr. Stone et al in the NEJM.

"This collection of information extends and solidifies our understanding of the role of drug-eluting stents by reaffirming the small magnitude of any increase in stent thrombosis, confirming the absence of an associated significant risk of death or heart attack for on-label indications, and calling for individualized physician decisions regarding the use of drug-eluting stents versus alternative revascularization approaches in currently off-label or extended use, until definitive trials for those uses are completed," said Donald S. Baim, M.D., Chief Medical and Scientific Officer for Boston Scientific.

Dr. Gregg Stone from Columbia University and the Cardiovascular Research Center and his co-authors examined patient level data on 3,513 patients from five clinical trials that randomly assigned them to receive either the TAXUS Stent (1,755 patients, including a small number who received a purely investigational higher dose - or moderate-release (MR) - formulation) or a similar bare-metal control stent (1,758 patients). These patients were then followed for up to four years, at which time the TAXUS Stent patients had a nearly 50 percent reduction (from 20.0% to 10.1%) in the need for a repeat procedure to treat a renarrowing, and a trend toward lower rates of death (6.1% vs. 6.6%) ( $p=0.68$ ) and death or large (Q-wave) heart attack (7.3% vs. 7.5%) ( $p=0.93$ ), compared to the patients who received the bare-metal control stent. Using the original protocol definition, there was a slight numerical excess of stent clotting (1.3% in the TAXUS Stent arm, versus 0.9% in the bare-metal arm), which failed to reach statistical significance ( $p=0.30$ ). Looking only at thrombosis events occurring beyond the first year, and including both moderate- and slow-release versions of the TAXUS stent, the study confirmed the previously reported small (0.4%, or about one event per 500 patient years) but statistically significant ( $p=0.028$ ) increase for the TAXUS Stent compared to the bare-metal control stent, which Boston Scientific's investigators have reported since March 2005. Similar examination comparing 878 patients who received Cordis' Cypher(R) sirolimus-eluting coronary stent (Cypher Stent) to 870 patients who received a bare-metal control stent also showed a significant reduction in repeat procedures, but showed a trend toward higher rates of death (6.7% vs. 5.3%) ( $p=0.23$ ) and death or large (Q-wave) MI (8.2% vs. 6.4%) ( $p=0.14$ ), and a similar and equally statistically significant (0.6%,  $p=0.025$ ) increase in stent thrombosis after one year for the Cypher Stent compared to the bare-metal control stent.

Dr. Christian Spaulding and co-authors from the Thoraxcenter in Rotterdam also examined the same patient level data on 878 patients who received the Cypher Stent and 870 patients who received a bare-metal control stent. Their findings were similar to those of Stone et al regarding the slight but not statistically significant increased incidence of death (6.7% vs. 5.4%) ( $p=0.28$ ) and death or Q-wave heart attack (8.2% vs. 6.5%) ( $p=0.17$ ) in the Cypher Stent compared to the bare-metal group. In the subgroup of 428 patients with diabetes, however, there was a highly significant increase in death for patients treated with the Cypher Stent versus the bare-metal control stent (12.2% versus 4.4%) ( $p=0.008$ ). At the December 7-8 FDA advisory panel meeting on drug-eluting stents (DES), Boston Scientific had presented data that the 715 patients with diabetes in its TAXUS Stent trials had similar or lower rates of death (9.2% DES vs. 10.7% BMS) ( $p=0.78$ ), with a significant reduction in repeat procedures (13.4% vs. 24.9%) ( $p<0.0001$ ), for the TAXUS Stent versus the bare-metal control stents, up to four years of follow up (1).

Dr. Adnan Kastrati and co-authors reported a separate meta-analysis of clinical trials assessing the relative safety of the Cypher Stent versus bare-metal stents (some with follow up as short as 12 months), and confirmed the trend toward excess mortality for the Cypher Stent versus BMS in diabetics, which did not show statistical significance as seen in the Dr. Patrick Serruys analysis of four Cordis pivotal trials at four-year follow up.

Dr. Laura Mauri and co-authors from the Harvard Clinical Research Center examined patient-level data from a sub-set of 2,797 patients who were randomly assigned to receive either the commercialized (slow-release, or SR) formulation of the TAXUS Stent or a similar BMS, and then followed for up to four years. Instead of the original (protocol) definition of stent thrombosis, they used the Academic Research Consortium (ARC) definitions of definite or probable stent thrombosis, and found no statistically significant differences in stent clotting overall for either the TAXUS Stent or the Cypher Stent compared to their respective bare-metal controls. Cumulatively in years one through four, the rates of stent thrombosis were 0.9% for the TAXUS Stent vs. 0.6% for BMS, and 0.9% for Cypher vs. 0.4% for BMS.

These observations were echoed in a Perspective piece in the March 8th edition of the NEJM by Dr. Andrew Farb and Ashley Boam (both of the FDA), who also summarized the findings of the FDA advisory panel, writing: "when drug-eluting stents are used for their approved indications, the risk of thrombosis does not outweigh their advantages over bare-metal stents in reducing the rate of



repeated revascularization " In addition, the authors emphasized that further " . . . randomized controlled trials . . . are needed to determine the best treatment strategies for lesions in patients with common, complex conditions" in which drug-eluting stents are now used beyond the current label indications. As examples, they cited three such trials that are already ongoing with Boston Scientific support, comparing drug-eluting stents to therapeutic alternatives in patient groups that lie outside current label indications.

Dr. Bo Lagerqvist, et al authored an article in the same edition of the NEJM describing results from the Swedish Coronary Angiography and Angioplasty Registry, which is the subject of a separate Boston Scientific press release today.

Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices whose products are used in a broad range of interventional medical specialties. For more information, please visit: [www.bostonscientific.com](http://www.bostonscientific.com).

This press release contains forward-looking statements. The Company wishes to caution the reader of this press release that actual results may differ from those discussed in the forward-looking statements and may be adversely affected by, among other things, risks associated with product development and commercialization, clinical trials, regulatory approvals, competitive offerings, intellectual property, the company's overall business strategy and other factors described in the Company's filings with the Securities and Exchange Commission.

CONTACT: Paul Donovan  
508-650-8541 (office)  
508-667-5165 (mobile)  
Media Relations  
Boston Scientific Corporation

Dan Brennan  
508-650-8538 (office)  
617-459-2703 (mobile)  
Investor Relations  
Boston Scientific Corporation

(1) The Company is currently sponsoring the collection of clinical data to support an application to the U.S. Food and Drug Administration to expand the TAXUS Stent's labeled indications for use in the United States to include diabetic patients. The safety and effectiveness of the TAXUS Express(TM) Stent have not been established in patients with diabetes.

SOURCE: Boston Scientific Corporation  
-0- 02/12/2007  
/CONTACT: Paul Donovan, Media Relations, +1-508-650-8541, or mobile, +1-508-667-5165, or Dan Brennan, Investor Relations, +1-508-650-8538, or mobile, +1-617-459-2703, both of Boston Scientific Corporation/  
/Web site: <http://www.bostonscientific.com/>  
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CO: Boston Scientific Corporation  
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SU: PDT

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5644 02/12/2007 17:00 EST <http://www.prnewswire.com>

# EXHIBIT 15

**GUIDANT**

Vascular Intervention



# January 1998

## U.S. Market Overview

**C O N F I D E N T I A L***Senior Staff*

Barclay, B	S214
Calfee, Richard	Houston
Howard, G	S212
Huss, B	S232
Johnson, G	S121
Larson, B	T500
Martlage, D	S211
McInnes, P.	T520
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*Global Marketing*  
(54 copies)

S112

*Temecula*

Fairchild, J	T120
Winton, B.	T400

*Directors*

Amoss, S.	S112
Castro, T.	S214
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Crall, C.	T540
Crapenholt, M	S214
Degois-Sainz, M.	S311
Douthitt, T	S112
Esselstein, B.	T120
Garfield, G	S214
Hirsch, E.	S214
King, G.	GDT-Jpn
Lyss, S	S112
Malito, O	S116
Mariani, P	S216
Mondry, M	S214
Muller, P.	S116
Nayak, V	S120
Nishimura, M	S112
Orlglas-Wedekind, M.	S112
Saltman, B.	S135
Schneiderman, G.	S214
Sirhan, M	S238
Spaulding, R.	S232

*Finance*

Bartels, S	S216
------------	------

*Business Development*

Bertonis, J.	S214
Gasson, J.	S214
Nemeth, J	S214
Zavelson, L.	S214

*GSC*

Antinori, D. - GDT - SE Ofc
Baumgardt, J. - GDT HQ, Indy
Blanchard, T. - GDT HQ, Indy
Davis, B. - S001
Ethridge, J. - S001
Harrold, M. - GDT - NE Ofc
Hopper, P. - GDT - West
Neupert, J. - GDT HQ, Indy
Rhatigan, K. - S001
Rieth, B. - GDT HQ, Indy
Sherman, M. - GDT HQ, Indy

Please forward questions regarding this distribution list to Linh Ho, ext. 53585

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## USMO Executive Summary

### January 1998

Beginning with the January 1997 data collection the USMO cath lab panel started reporting units used instead of units sold. This should capture units received free of charge and better reflect the current demand trends in the market.

#### **Dilatation Catheter Business**

##### **Average Daily Sales (Units)**

##### **Dilatation Catheter Market**

December	January	% Chg.
4551	4573	0%

Market ADS is calculated using rolling ACS share of units used from cath lab panel and ACS units sold.

ACS Segment	December	January	% Change
RX	1,046	1,070	2%
Perfusion	157	147	-6%
OTW	120	92	-24%
IS	3	3	39%
Total DC Units	1,326	1,312	-1%

In January, SciMed (47%) lost 2pp while ACS (29%) was stable. JJIS/Cordis (13%) and Schneider(7%) each gained 1pp while Medtronic (3%) and USCI were (1%) stable.

Top Selling Dilatation Catheter: SciMed Ranger (18%, stable)

#### **Dilatation Catheter Market Segments**

##### **Market Segment Mix**

OTW	65%	(-1 pp)	Perfusion	4%	(-1 pp)
RX	29%	(+2 pp)	IS	2%	(stable)

##### **Over-the-Wire**

Manufacturer	Share	Change
SciMed/Mansfield	58%	(stable)
JJIS/Cordis	19%	(+1 pp)
ACS	6%	(-1 pp)
Medtronic	4%	(stable)

Top Product: SciMed Ranger (27%, -3 pp)

Comments: JJIS/Cordis gained 1pp while ACS lost 1pp. SciMed and Medtronic were stable

##### **Rapid Exchange**

Manufacturer	Share	Change
ACS	74%	(stable)
Schneider/Shiley	21%	(+1 pp)
SciMed/Mansfield	4%	(-1 pp)
Medtronic	1%	(stable)

Top Product Line: ACS Rocket (52%, +17 pp)

Comments: ACS and Medtronic were stable. Schneider gained 1pp in the RX market segment while SciMed lost 1pp.

#### **High Pressure/Non-Compliant & Extended Pressure/Front-line**

##### **HP/NC (RBP > 14 ATM) as % of Business**

Nov	Dec	Jan
38%	39%	40%

##### **Extended Pressure (RBP = 9-14 ATM) as % of Business**

Nov	Dec	Jan
52%	53%	54%

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#### **Guide Wires**

Manufacturer	Share	Change
ACS	60%	(+3 pp)
SciMed/Mansfield*	26%	(-3 pp)
Cordis	9%	(stable)

#### **Coronary Stents**

Manufacturer	Share	Change
ACS	58%	(-5 pp)
AVE	18%	(+17 pp)
JJIS/Cordis	16%	(-7 pp)
Cook	5%	(-3 pp)
Medtronic	2%	(-1 pp)

#### **Vascular Intervention Unit Market Share - as a % of all devices (BDC & 2nd Gen.)**

Guidant	38%	(-1 pp)
SciMed/Boston Sci	34%	(-1 pp)
JJIS/Cordis	14%	(-1 pp)

Schneider/Shiley	4%	(stable)
Cook	2%	(-1 pp)
Medtronic	2%	(-1 pp)

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## 2ND GENERATION INTERVENTIONAL DEVICES

ACTUAL NUMBERS		Jan 1997	Feb 1997	Mar 1997	Apr 1997	May 1997	Jun 1997	Jul 1997	Aug 1997	Sep 1997	Oct 1997	Nov 1997	Dec 1997	Jan 1998
All SciMed/Mansfield DVI	All Stents	86%	87%	87%	87%	87%	88%	89%	88%	87%	89%	87%	89%	87%
	Rotablator	12%	11%	11%	11%	11%	11%	9%	10%	12%	9%	11%	10%	12%
	DVIATH	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	0%	1%
% of all devices (BDC ± All Tech.)		31%	31%	31%	33%	34%	37%	32%	35%	36%	36%	37%	38%	38%

## CORONARY STENT SHARE

ACTUAL NUMBERS		Jan 1997	Feb 1997	Mar 1997	Apr 1997	May 1997	Jun 1997	Jul 1997	Aug 1997	Sep 1997	Oct 1997	Nov 1997	Dec 1997	Jan 1998
ACS	ACS MULTILINK										31%	61%	64%	58%
AVE	AVE MICRO STENT II												1%	18%
JJIS/Cordis	PALMAZ-SCHATZ	94%	92%	92%	94%	90%	80%	68%	65%	67%	47%	25%	23%	13%
Cook	COOKGR2								34%	32%	21%	10%	8%	5%
JJIS/Cordis	J&J CROWN													3%
Medtronic	Wiktor									0%		3%	3%	2%
Cook	CookGR1 & GR2	6%	8%	8%	6%	10%	20%	31%	1%					
Cook	CookGR1									1%				

\* As of Aug 1997, the GR1 and GR2 were split.

## ACS CORONARY STENT AVERAGE DAILY SALES (DOMESTIC)

ACS CORONARY STENT SYSTEMS (CORONARY STENTS)		Jan-97	Feb-97	Mar-97	Apr-97	May-97	Jun-97	Jul-97	Aug-97	Sep-97	Oct-97	Nov-97	Dec-97	Jan-98
ACS Multi-Link											1334	1896	1864	1484
ACS Multi-Link HP														51
Total ACS Coronary Stents											1334	1896	1864	1535

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## USMO Executive Summary

### January 1999

#### Coronary Stents

##### Average Daily Sales (Units)

	Dec	Jan	% Chg.
Market*	3280	3322	1%
Guidant	1760	1779	1%

Manufacturer	Share	Change
Guidant	52%	(+3 pp)
Boston Scientific	28%	(-3 pp)
AVE	16%	stable
JJIS/Cordis	3%	(-1 pp)

Top Selling Coronary Stent: ACS ML Duet 48% (+5pp)

\* Market ADS is calculated using ACS unit share and ACS units sold with adjustments for inventory levels.

#### Dilatation Catheter Business

##### Market Average Daily Sales (Units)\*\*

Dec	Jan	% Chg.
3947	3652	-7%

##### Guidant Average Daily Sales (Units)

Segment	Dec	Jan	% Change
RX	859	823	-4%
OTW	243	238	-2%
Perfusion	54	52	-3%
IS	-	-	n/a
	1,156	1,114	-4%

\*\*Market ADS is calculated using rolling ACS share

of units used from cath lab panel and rolling ACS units sold.

In January, SciMed/Schneider (59%) lost 3 pp. Guidant (31%) gained 2 pp. JJIS/Cordis (6%) lost 1 pp and Medtronic/USCI/AVE (3%) gained 1 pp.

Top Selling Dilatation Catheter: Scimed Ranger (20%, -2pp).

#### Dilatation Catheter Market Segments

##### Market Segment Mix

OTW	63%	(-3 pp)	Perfusion	2%	(stable)
RX	33%	(+2 pp)	IS	2%	(stable)

##### Over-the-Wire

Manufacturer	Share	Change
SciMed/Schneider	75%	(-2 pp)
JJIS/Cordis	10%	(stable)
Guidant	10%	(stable)
Medtronic/USCI/AVE	4%	(+1 pp)

Top Product: SciMed Ranger (33%, -1 pp)

Comments: SciMed/Schneider lost 2pp while Medtronic/USCI/AVE gained 1pp. Guidant and Cordis were stable

##### Rapid Exchange

Manufacturer	Share	Change
Guidant	71%	(+1 pp)
SciMed/Schneider	29%	(-1 pp)

Top Product: ACS Rocket (61%, stable)

Comments: Guidant gained 1pp while Scimed/Schneider lost 1 pp.

#### High Pressure/Non-Compliant & Extended Pressure/Front-line

##### HP/NC (RBP > 14 ATM) as % of Business

Nov	Dec	Jan
39%	37%	37%

##### Ext. Pressure (RBP = 9-14 ATM) as % of Business

Nov	Dec	Jan
57%	59%	56%

#### Guide Wires

Manufacturer	Share	Change
Guidant	60%	(+1 pp)
SciMed/Schneider	30%	(stable)
Cordis	6%	(-1 pp)
Medtronic/AVE/USCI	2%	(stable)

#### Guiding Catheters

Manufacturer	Share	Change
SciMed/Schneider	38%	(-1 pp)
JJIS/Cordis	33%	(+1 pp)
Guidant	16%	(stable)
MDT/AVE/USCI	12%	(stable)

## 2ND GENERATION INTERVENTIONAL DEVICES

ACTUAL NUMBERS		Jan 1998	Feb 1998	Mar 1998	Apr 1998	May 1998	Jun 1998	Jul 1998	Aug 1998	Sep 1998	Oct 1998	Nov 1998	Dec 1998	Jan 1999
		87%	89%	91%	91%	92%	92%	91%	92%	92%	92%	92%	92%	93%
BSX/SciMed/Schneider	All Stents	12%	10%	8%	9%	7%	7%	8%	8%	7%	8%	7%	7%	7%
	ROTABLATOR													
% of all devices (BDC + Alt. Tech.)		38%	40%	40%	41%	42%	43%	43%	45%	46%	44%	45%	46%	47%

## CORONARY STENT SHARE BY MANUFACTURER

ACTUAL NUMBERS		Jan 1998	Feb 1998	Mar 1998	Apr 1998	May 1998	Jun 1998	Jul 1998	Aug 1998	Sep 1998	Oct 1998	Nov 1998	Dec 1998	Jan 1999
		59%	54%	48%	47%	47%	44%	39%	35%	29%	30%	39%	49%	52%
	ACS													
	Boston Scientific	18%	27%	34%	36%	39%	44%	45%	19%	34%	32%	33%	31%	28%
	AVE	16%	14%	15%	15%	12%	10%	9%	39%	31%	32%	24%	16%	16%
	JJIS/Cordis	5%	4%	3%	2%	2%	1%	1%	6%	5%	5%	4%	4%	3%
	Cook	2%		1%	1%		1%	1%	1%	0%	1%	0%	0%	
	Medtronic													

## CORONARY STENT SHARE

ACTUAL NUMBERS		Jan 1998	Feb 1998	Mar 1998	Apr 1998	May 1998	Jun 1998	Jul 1998	Aug 1998	Sep 1998	Oct 1998	Nov 1998	Dec 1998	Jan 1999
		3%	7%	10%	10%	16%	32%	38%	14%	15%	23%	23%	43%	48%
BSX/SciMed/Schneider	ACS MULTILINK DUET													
Medtronic/AVE/USCI	BSX NIR													
JJIS/Cordis	GFX													
ACS	J&J CROWN													
Medtronic/AVE/USCI	ACS MULTILINK	58%	53%	41%	36%	34%	31%	27%	35%	29%	30%	22%	14%	14%
BSX/SciMed/Schneider	AVE MICRO STENT II	18%	27%	34%	33%	23%	12%	7%	22%	17%	17%	10%	4%	3%
ACS	BSX RADIUS	0%	1%	7%	11%	13%	14%	12%	4%	2%	2%	1%	2%	2%
BSX/SciMed/Schneider	Multi-Link HP								6%	3%	4%	3%	2%	1%
JJIS/Cordis	NIR W/SOX	13%	7%	5%	5%	2%	1%	1%	12%	12%	13%	6%	3%	1%
Cook	Palmaz Schatz	5%	4%	3%	2%	2%	1%	1%	1%	16%	5%	1%	1%	0%
Medtronic/AVE/USCI	GR2	2%		1%	1%		1%	1%	1%		1%			
	Wiktor Rival													

As of Sept 98, the NIR Share was split to NIR and NIR w/SOX

## ACS CORONARY STENT AVERAGE DAILY SALES (DOMESTIC)

	Jan-98	Feb-98	Mar-98	Apr-98	May-98	Jun-98	Jul-98	Aug-98	Sep-98	Oct-98	Nov-98	Dec-98	Jan-99
ACS Multi-Link Duet	1,484	1,210	1,071	980	982	825	716	566	447	371	938	1,690	1,738
ACS Multi-Link	51	258	361	447	480	442	420	423	435	434	239	40	28
ACS Multi-Link HP													
Total ACS Coronary Stents	1,535	1,469	1,432	1,428	1,462	1,268	1,136	988	882	805	1,177	1,730	1,766

# USMO Coronary Executive Summary January 2000

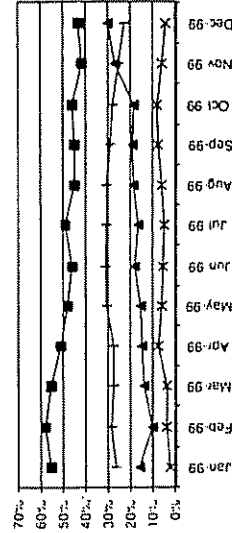
Rolling numbers are used in the BDC and GW categories. These numbers are in red to allow easy identification.

## Coronary Stents

Average Daily Sales (Units)			
	Dec-99	Jan-00	% Chg.
Market (estimate)	3477	3557	2%
Guidant Sales	1737	1632	-6%
Guidant Share	42%	43%	3%

Unit Share (%)			
Manufacturer	Dec-99	Jan-00	Change
Guidant	42%	43%	1 pp
Boston Scientific	26%	23%	-3 pp
Medtronic AVE	27%	30%	3 pp
JJIS/Cordis	6%	4%	-2 pp

The Tristar launch in December resulted in only a marginal share increase in January. Due to the late launch only a limited number of cath labs had the Tristar available in January. Out of the 185 cath labs reporting data, only 107 labs reported any Tristar usage. While this is more than 50% of the labs, some of them might have received the Tristar towards the end of the month. Medtronic gained 3 pp at the expense of BSX and JJJ. The decline in share gain from 8pp in December to 3pp in January implies that Medtronic is losing momentum.



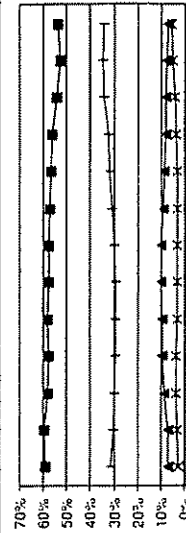
■ Guidant  
+ Boston Scientific  
▲ Medtronic AVE  
× JJIS/Cordis

## Dilatation Catheter Business

Average Daily Sales (Units)			
	Dec-99	Jan-00	% Chg.
Market (estimate)	3765	3728	-1%
Guidant Sales	1,342	1,237	-8%
Guidant Share	35%	34%	-1%

Unit Share (%)			
Manufacturer	Dec-99	Jan-00	Change
BSX/SciMed/Schneider	53%	53%	1 pp
Guidant	35%	34%	stable
JJIS/Cordis	8%	7%	-1 pp
Medtronic/AVE/USCI	5%	5%	1 pp

GDT BDC market share increased in January to 35% (non-rolling) share. When combined with the 33% December share, the 2 month rolling number is 34%. This appears to be the result of full availability of the Pholton balloon that gained 4pp in the OTW segment. GDT lost 3pp in the RX segment while gaining 2pp in the larger OTW segment resulting in an overall share increase.

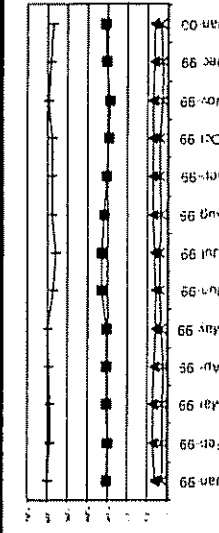


■ BSX/SciMed/Schneider  
+ Guidant  
▲ JJIS/Cordis  
× Medtronic/AVE/USCI

## Guide Wires

Average Daily Sales (Units)			
	Dec-99	Jan-00	% Chg.
Market (implied)*	4971	4464	-10%
Guidant Sales	2,890	2,536	-12%
Guidant Share	58%	57%	-2%

Unit Share (%)			
Manufacturer	Dec-99	Jan-00	Change
Guidant	58%	57%	-1 pp
BSX/SciMed/Schneider	20%	31%	1 pp
JJIS/Cordis	7%	6%	stable
Medtronic/AVE/USCI	1%	1%	1 pp

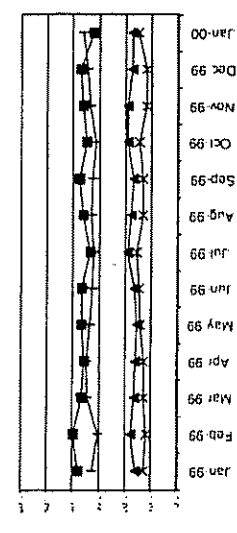


■ Guidant  
+ BSX/SciMed/Schneider  
▲ JJIS/Cordis  
× Medtronic/AVE/USCI

## Guiding Catheters

Average Daily Sales (Units)			
	Dec-99	Jan-00	% Chg.
Market (implied)*	4146	3734	-10%
Guidant Sales	710	641	-10%
Guidant Share	17%	17%	0%

Unit Share (%)			
Manufacturer	Dec-99	Jan-00	Change
JJIS/Cordis	34%	36%	2 pp
BSX/SciMed/Schneider	37%	32%	-5 pp
Guidant	17%	17%	stable
Medtronic/AVE/USCI	12%	15%	3 pp



■ JJIS/Cordis  
+ BSX/SciMed/Schneider  
▲ Guidant  
× Medtronic/AVE/USCI

\* Implied market size is calculated by dividing GDT unit sales by GDT unit share. This might not accurately reflect actual market size.



2ND GENERATION INTERVENTIONAL DEVICES														
ACTUAL NUMBERS		Jan-99	Feb-99	Mar-99	Apr-99	May-99	Jun-99	Jul-99	Aug-99	Sep-99	Oct-99	Nov-99	Dec-99	Jan-00
BSX/SciMed/Schneider	All	93%	94%	91%	92%	92%	92%	92%	93%	95%	97%	96%	95%	95%
	Rotablator	7%	6%	8%	8%	7%	8%	6%	1%	1%	3%	4%	5%	5%
CORONARY STENT SHARE BY MANUFACTURER														
ACTUAL NUMBERS		Jan-99	Feb-99	Mar-99	Apr-99	May-99	Jun-99	Jul-99	Aug-99	Sep-99	Oct-99	Nov-99	Dec-99	Jan-00
RX Stent Share OTW Stent Share	Guidant	52%	55%	58%	55%	51%	48%	46%	45%	45%	45%	46%	42%	43%
	Boston Scientific	28%	26%	28%	27%	27%	31%	31%	43%	31%	29%	28%	26%	23%
	Medtronic AVE	16%	16%	10%	14%	15%	15%	18%	16%	19%	19%	19%	27%	30%
	JJIS/Cordis	3%	2%	4%	4%	7%	6%	5%	5%	6%	7%	8%	6%	4%
	Cook	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
CORONARY STENT SHARE														
ACTUAL NUMBERS		Jan-99	Feb-99	Mar-99	Apr-99	May-99	Jun-99	Jul-99	Aug-99	Sep-99	Oct-99	Nov-99	Dec-99	Jan-00
BSX/SciMed/Schneider	Guidant													1%
	ACS ML RX Tristar													22%
	Medtronic/AVE/USCI/E/MEDTRONIC S670 D OTW													16%
	SCIMED NIR PRIMO													9%
	BSX/SciMed/Schneider													13%
	-BSX NIR on Ranger	27%	24%	26%	25%	25%	19%	16%	12%	13%	13%	14%	12%	11%
	**ACS RX MULTILINK DUET	48%	51%	51%	53%	49%	31%	27%	26%	30%	31%	30%	28%	10%
	Guidant													0%
	ACS ML OTW Tristar													7%
	Medtronic/AVE/USCI/E/MEDTRONIC S670 D RX													3%
	Medtronic/AVE/USCI													4%
	AVE/MEDTRONIC S540													5%
	Guidant													11%
ACS OTW Multi-Link Duet													13%	
Medtronic/AVE/USCI					8%	13%	13%	15%	15%	16%	16%	13%	9%	
AVE GFX 2										2%	2%	5%	2%	
J&J CROSSFLEX LC						5%	3%	4%	3%	3%	2%	2%	1%	
JJIS/Cordis					1%	0%	3%	2%	1%	2%	2%	2%	1%	
JJIS/Cordis		1%	2%	3%	1%	0%	3%	2%	1%	2%	2%	2%	1%	
Guidant		3%	2%	4%	3%	2%	2%	2%	1%	1%	1%	1%	1%	
JJIS/Cordis		3%	2%	4%	3%	2%	2%	2%	1%	1%	1%	1%	1%	
ACS MULTILINK		3%	2%	4%	2%	1%	2%	2%	2%	2%	2%	1%	1%	
**As of Sept 99, the NIR ON RANGER was split from NIR w/SOX. **Dec 98 through May 99 includes OTW Duets.														
GUIDANT CORONARY STENT AVERAGE DAILY SALES														
		Jan-99	Feb-99	Mar-99	Apr-99	May-99	Jun-99	Jul-99	Aug-99	Sep-99	Oct-99	Nov-99	Dec-99	Jan-00
Tristar	ACS Multi-Link Duet	1,738	1,909	2,091	1,908	1,878	1,669	1,534	1,475	1,649	1,387	1,474	1,493	465
	ACS Multi-Link	28	23	14	9	14	8	5	4	6	4	3	5	2
	ACS Multi-Link HP	13	8	7	4	5	3	1	4	2	2	2	2	2
	Total GUIDANT Coronary Stents	1,779	1,940	2,113	1,921	1,897	1,680	1,540	1,483	1,657	1,393	1,479	1,737	1,632

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**January 2001**

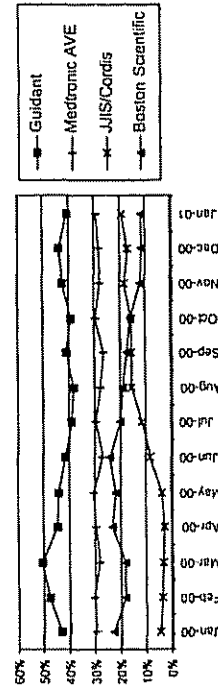
Rating numbers are used in the BDC and GW categories. These numbers are in red to allow easy identification.

### Coronary Stents

Average Daily Sales (Units)			Unit Share (%)		
Dec-00	Jan-01	% Chg.	Manufacturer	Dec-00	Jan-01
Market (estimat)	4002	4139	3%	Guidant	44%
Guidant Sales	2744	1409	-49%	Medtronic AVE	28%
Guidant Share	44%	41%	-7%	JJIS/Cordis	17%
				Boston Scientific	11%

Change: -3 pp, 1 pp, 2 pp, stable

GDT stent share decreased to 41% in January. January stent ADUs dropped by 49% when compared to December sales. This decrease is the result of bulk orders shipped during the last two weeks of December.

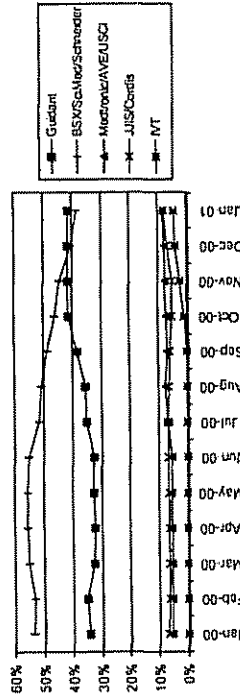


### Dilatation Catheter Business

Average Daily Sales (Units)			Unit Share (%)		
Dec-00	Jan-01	% Chg.	Manufacturer	Dec-00	Jan-01
Market (estimat)	3704	3690	0%	Guidant	42%
Guidant Sales	1913	1511	-21%	BSX/SchMed/Schneider	40%
Guidant Share	42%	41%	-2%	Medtronic/AVE/USCI	8%
				JJIS/Cordis	7%

Change: -1 pp, -2 pp, 1 pp, 1 pp

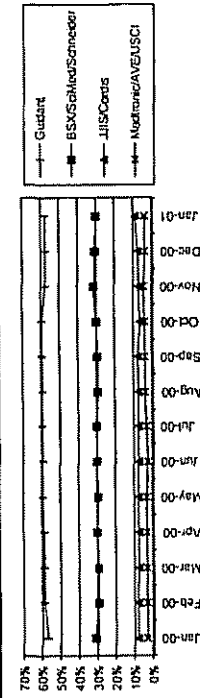
Guidant's two-month rolling share decreased to 41% and sales were 21% lower than in December. GDT's December sales were augmented by bulk orders. Considering this factor, January sales were strong. GDT maintained its market leadership in BDCs. BSX is launching the Maverick BDC in the OTW and RX segments. The IVT cutting balloon has captured 4% of the BDC market. IVT was acquired by BSX in February of 2001.



### Guide Wires

Average Daily Sales (Units)			Unit Share (%)		
Dec-00	Jan-01	% Chg.	Manufacturer	Dec-00	Jan-01
Market (implied)	4998	5105	2%	Guidant	58%
Guidant Sales	2,882	2,936	2%	BSX/SchMed/Schneider	31%
Guidant Share	58%	58%	0%	JJIS/Cordis	8%
				Medtronic/AVE/USCI	4%

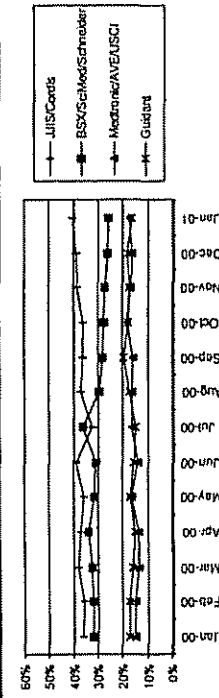
Change: stable, -1 pp, 1 pp, stable



### Guiding Catheters

Average Daily Sales (Units)			Unit Share (%)		
Dec-00	Jan-01	% Chg.	Manufacturer	Dec-00	Jan-01
Market (implied)	4287	4910	15%	JJIS/Cordis	39%
Guidant Sales	775	801	3%	BSX/SchMed/Schneider	26%
Guidant Share	18%	16%	-10%	Medtronic/AVE/USCI	17%
				Guidant	18%

Change: 1 pp, -1 pp, 1 pp, -2 pp



\* Implied market size is calculated by dividing GDT unit sales by GDT unit share. This might not accurately reflect actual market size.



## 2ND GENERATION INTERVENTIONAL DEVICES

ACTUAL NUMBERS	All BSX/SciMed/Schneider	Jan-00	Feb-00	Mar-00	Apr-00	May-00	Jun-00	Jul-00	Aug-00	Sep-00	Oct-00	Nov-00	Dec-00	Jan-01
		95%	95%	95%	95%	95%	95%	95%	96%	95%	95%	95%	96%	96%
	All Stents ROTOBLADER	5%	5%	5%	5%	5%	5%	5%	4%	4%	4%	4%	3%	3%

## CORONARY STENT SHARE BY MANUFACTURER

ACTUAL NUMBERS		Jan-00	Feb-00	Mar-00	Apr-00	May-00	Jun-00	Jul-00	Aug-00	Sep-00	Oct-00	Nov-00	Dec-00	Jan-01
	Guidant	43%	48%	50%	45%	44%	41%	39%	38%	41%	39%	42%	44%	41%
	Medtronic AVE	30%	31%	28%	30%	31%	27%	30%	28%	26%	30%	28%	28%	29%
	JJIS/Cordis	4%	4%	3%	3%	4%	8%	11%	15%	15%	15%	18%	17%	19%
	Boston Scientific	23%	18%	18%	23%	22%	24%	20%	19%	17%	16%	12%	11%	11%
	Biocompatibles													
	% RX Stents	51%	52%	53%	50%	47%	50%	55%	52%	54%	46%	50%	48%	47%
	% OTW Stents	49%	48%	47%	50%	53%	50%	45%	48%	46%	54%	50%	52%	53%

## CORONARY STENT SHARE

ACTUAL NUMBERS	Guidant JUIS/Cordis Medtronic/AVE/USCI Medtronic/AVE/USCI Medtronic/AVE/USCI BSX/SciMed/Schneider BSX/SciMed/Schneider Medtronic/AVE/USCI Medtronic/AVE/USCI BSX/SciMed/Schneider JUIS/Cordis Guidant	Jan-00	Feb-00	Mar-00	Apr-00	May-00	Jun-00	Jul-00	Aug-00	Sep-00	Oct-00	Nov-00	Dec-00	Jan-01
		16%	7%	14%	9%	14%	10%	15%	10%	7%	15%	15%	16%	18%
	ACS ML RX Tetra					2%	7%	10%	15%		10%	24%	24%	27%
	JU BX Velocity OTW													
	ACS ML OTW Tetra													
	AVE/MEDTRONIC S670 D OTW					14%	11%	11%	12%	11%	12%	9%	12%	11%
	AVE/MEDTRONIC S670 D RX					10%	9%	11%	9%	10%	9%	8%	9%	8%
	AVE/MEDTRONIC S660 D OTW					3%	3%	4%	4%	3%	5%	3%	4%	4%
	AVE/MEDTRONIC S660 D RX					10%	8%	6%	5%	6%	5%	4%	3%	4%
	SCIMED NIR WISOX OTW					0%	8%	10%	10%	8%	8%	4%	4%	3%
	BSX NIR Royal					1%	2%	2%	3%	2%	3%	3%	3%	2%
	AVE/MEDTRONIC S660 D RX										0%	2%	2%	2%
	AVE/MED BESTENT2 OTW										0%	0%	1%	1%
	AVE/MED BESTENT2 RX										0%	0%	1%	1%
	NIR Royal Advance										1%	1%	1%	1%
	NIR ROYAL ELITE										1%	1%	1%	1%
	BX Velocity Hepatocot OTW										0%	1%	0%	1%
	ACS ML RX Ultra										1%	1%	1%	1%

## GUIDANT CORONARY STENT AVERAGE DAILY SALES

ACTUAL NUMBERS	ML Tetra ML Ultra ML Tristar Other Stents	Jan-00	Feb-00	Mar-00	Apr-00	May-00	Jun-00	Jul-00	Aug-00	Sep-00	Oct-00	Nov-00	Dec-00	Jan-01
		1,163	1,675	2,005	1,652	1,676	2,273	1,074	1,103	1,638	698	182	49	24
		469	135	44	16	24	16	9	9	9	7	1	0	1
	Total GUIDANT Coronary Stents	1,632	1,810	2,049	1,668	1,700	2,289	1,083	1,112	1,631	1,256	1,557	2,744	1,409

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# Confidential USMO Coronary Executive Summary January 2002 Confidential

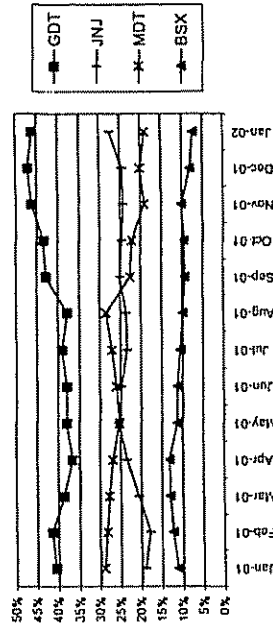
January 2002

Rolling numbers are used in the BDC and GW categories. These numbers are in red to allow easy identification.

## Coronary Stents

Average Daily Sales (Units)				Unit Share (%)			
	Dec-01	Jan-02	% Chg.		Dec-01	Jan-02	Change
Market (estimate)	4365	4471	2%	GDT	47%	46%	-1 pp
Guidant Sales	3239	1642	-49%	JNJ	25%	27%	3 pp
Guidant Share	47%	45%	-2%	MDT	20%	19%	-1 pp
				BSX	8%	7%	-1 pp

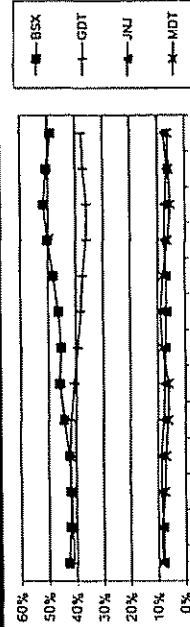
GDT unit sales in January were 49% lower than December sales. This is due to the December bulking. GDT stent share decreased to 46%. MDT and BSX also lost 1% each. JNJ gained the 3% stent share. MDT's exit and sale in September continues to have a delayed impact on the RX market. MDT's RX market share in January was 8%. It is expected that MDT will continue to maintain RX implant share without any sales over the next couple months.



## Dilatation Catheter Business

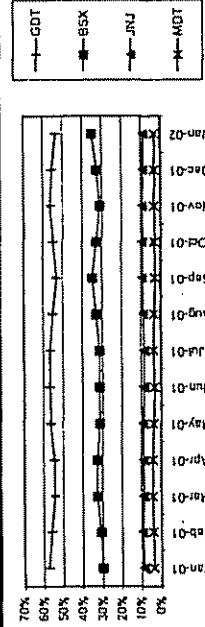
Average Daily Sales (Units)				Unit Share (%)			
	Dec-01	Jan-02	% Chg.		Dec-01	Jan-02	Change
Market (estimate)	3944	3988	1%	BSX	51%	49%	-2 pp
Guidant Sales	1,696	1,427	-16%	GDT	37%	38%	stable
Guidant Share	37%	36%	1%	JNJ	6%	7%	1 pp
				MDT	6%	6%	stable

GDT's 2 month rolling market share essentially stayed stable at 38%. BSX lost 2% while JNJ gained 1%. GDT unit sales in January were 16% lower than December sales due to December bulking.



## Guide Wires

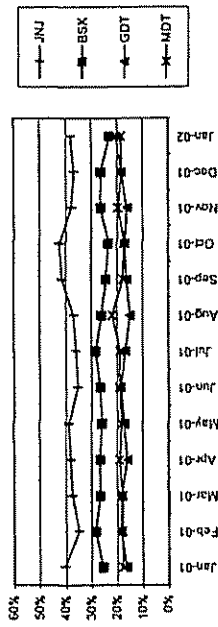
Average Daily Sales (Units)				Unit Share (%)			
	Dec-01	Jan-02	% Chg.		Dec-01	Jan-02	Change
Market (implied)*	5664	5513	-3%	GDT	55%	53%	-2 pp
Guidant Sales	3,135	2,949	-6%	BSX	33%	35%	2 pp
Guidant Share	55%	53%	-3%	JNJ	9%	9%	stable
				MDT	3%	3%	stable



## Guiding Catheters

Average Daily Sales (Units)				Unit Share (%)			
	Dec-01	Jan-02	% Chg.		Dec-01	Jan-02	Change
Market (implied)*	3830	3479	-9%	JNJ	37%	38%	1 pp
Guidant Sales	702	708	1%	BSX	26%	23%	-3 pp
Guidant Share	18%	20%	11%	GDT	18%	20%	2 pp
				MDT	16%	18%	stable

\* Implied market size is calculated by dividing GDT unit sales by GDT unit share. This might not accurately reflect actual market size.



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CORONARY STENTS													
CORONARY STENT SHARE BY MANUFACTURER													
ACTUAL NUMBERS	Jan-01	Feb-01	Mar-01	Apr-01	May-01	Jun-01	Jul-01	Aug-01	Sep-01	Oct-01	Nov-01	Dec-01	Jan-02
GDT	41%	41%	39%	37%	38%	38%	39%	36%	43%	43%	46%	47%	46%
JNJ	19%	18%	21%	23%	25%	25%	23%	24%	25%	25%	24%	25%	27%
MDT	29%	28%	28%	27%	25%	26%	27%	26%	23%	22%	19%	20%	19%
BSX	11%	12%	13%	13%	11%	11%	10%	10%	9%	10%	10%	8%	7%
Biocompatibles					0%				0%	0%	0%	0%	0%
CORONARY STENT SHARE BY PRODUCT													
ACTUAL NUMBERS	Jan-01	Feb-01	Mar-01	Apr-01	May-01	Jun-01	Jul-01	Aug-01	Sep-01	Oct-01	Nov-01	Dec-01	Jan-02
ACS ML Penia RX						3%	10%	13%	21%	22%	23%	25%	24%
MDT				2%	5%	7%	8%	10%	8%	10%	9%	9%	10%
BSX				11%	11%	10%	8%	8%	9%	8%	8%	6%	9%
JNJ	18%	16%	17%					5%	10%	8%	10%	9%	9%
ACS ML Penia OTW					0%	2%	5%	5%	8%	7%	7%	8%	8%
MDT				6%	7%	7%	8%	8%	8%	6%	6%	6%	7%
JNJ	1%	2%	4%	7%	8%	7%			0%	3%	2%	3%	4%
ACS ML RX PIXEL										2%	3%	3%	4%
MDT										0%	1%	2%	3%
BSX										3%	3%	3%	3%
ACS ML Pixel OTW	4%	3%	3%	3%	5%	8%	8%	8%	6%	6%	3%	4%	2%
MDT				1%	2%	2%	2%	3%	3%	3%	2%	3%	2%
BSX				2%	2%	2%	3%	3%	3%	2%	2%	2%	2%
JNJ	27%	26%	27%	22%	25%	21%	14%	13%	6%	4%	2%	1%	2%
MDT	11%	11%	10%	8%	5%	3%	2%	2%	1%	2%	2%	1%	1%
BSX				3%	3%	3%	1%	1%	1%	1%	1%	1%	1%
NIR Royal Elite OTW	1%	1%	1%	1%	1%	1%	2%	2%	2%	2%	2%	1%	1%
MDT	1%	4%	4%	2%	3%	3%	2%	2%	2%	1%	1%	1%	1%
BSX	2%	3%	3%	2%	2%	2%	2%	2%	2%	2%	1%	1%	1%
MDT	11%	11%	9%	9%	8%	9%	5%	5%	3%	2%	1%	1%	0%
BeStent 2 OTW	2%	2%	1%	2%	1%	1%	0%	1%	0%	1%	1%	0%	0%
GUIDANT CORONARY STENT AVERAGE DAILY SALES													
ACTUAL NUMBERS	Jan-01	Feb-01	Mar-01	Apr-01	May-01	Jun-01	Jul-01	Aug-01	Sep-01	Oct-01	Nov-01	Dec-01	Jan-02
ML Tetra	1,321	1,403	2,164	1,101	1,185	1,154	741	687	466	210	111	79	55
ML Penia					12	955	411	640	2,014	1,103	1,174	2,401	1,139
ML Ultra	63	71	77	64	64	65	58	59	80	61	66	85	62
ML Pixel								20	183	200	347	672	385
Total GUIDANT Coronary Stents	1,384	1,474	2,241	1,165	1,262	2,174	1,210	1,406	2,743	1,574	1,698	3,237	1,641
RX-OTW Stent Split													
Segment RX	47%	50%	50%	49%	52%	51%	55%	53%	50%	52%	53%	55%	52%
Segment OTW	53%	50%	50%	51%	48%	49%	45%	47%	50%	48%	47%	45%	48%

(\*Please note that data going back to April 01 has been corrected to reflect only OTW BX Velocity with Hepacool, as it is not available in RX.)

REMAINDER  
OF EXHIBIT  
REDACTED

# EXHIBIT 16

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ABBOTT CARDIOVASCULAR	)	
SYSTEMS INC. and ABBOT	)	
LABORATORIES INC.,	)	Civil Action No. 98-80 (SLR)
	)	(Consolidated with C.A. No. 98-314
Plaintiffs,	)	(SLR) and C.A. No. 98-316 (SLR))
	)	
v.	)	
	)	
MEDTRONIC VASCULAR, INC. and	)	
MEDTRONIC USA, INC.,	)	
	)	
Defendants.	)	
_____	)	

**DECLARATION OF JOEL K. KAHN, M.D.**

I, Joel K. Kahn, hereby declare as follows:

1. I am a medical doctor specializing in interventional cardiology. I am a certified specialist in internal medicine and a certified sub-specialist in cardiovascular medicine and interventional cardiology. After graduating summa cum laude from the University of Michigan Medical School in 1983, I was an internal medicine resident for three years at University Hospital in Ann Arbor, Michigan. I was then a cardiology fellow for three years at University of Texas Southwestern Medical Center and an advanced angioplasty fellow for one year at the Mid-America Heart Institute of St. Luke's Hospital, Kansas City, Missouri. My *curriculum vitae* is attached as Exhibit 1.

2. I currently perform approximately 400 invasive procedures per year, including 150-200 percutaneous coronary interventions ("PCI") per year. Another commonly used term for PCI is percutaneous transluminal coronary angioplasty ("PTCA") or "balloon angioplasty." Since 1986, I have performed approximately 5,000 PCI procedures. I have personally implanted

a number of different stents in human patients, including the Multi-Link family of stents and various stents sold by Medtronic.

3. I currently serve on the editorial board of the Journal of Interventional Cardiology. I previously served on the editorial board of Catheterization and Cardiovascular Intervention. In addition, I review and judge original research and peer reviewed articles submitted for publication in other medical journals on an *ad hoc* basis.

4. I have been retained in this matter by Advanced Cardiovascular Systems, Inc. ("ACS") as an expert on the clinical use of coronary and peripheral stents. I am being compensated at \$500 per hour for my time. I have been retained and compensated by ACS in other litigation matters, and testified at the trial in this case in February 2005.

5. I have been asked to opine on whether a court order precluding the sale in the U.S. of certain Medtronic stents, including the Microstent II, GFX, GFX 2, GFX 2.5, S540, S660, S670, S7, BeStent 2, Driver, MicroDriver, and Racer, would have any significant negative impact on patients suffering from coronary artery disease and other diseases typically treated with a stent. I have also been asked to opine on whether a court order that precluded Medtronic from introducing its Endeavor stent into the United States would have any significant negative impact on patients that could be treated with a drug-eluting stent ("DES").

6. In my practice as an interventional cardiologist, I have used many of the Medtronic stents listed in ¶ 5 above. Most recently, of those stents, I have primarily been using the Driver and MicroDriver stents. Both of these products are bare-metal (non-DES) stents used for the treatment of coronary artery disease.

7. I am also familiar with many (if not all) of the competing bare-metal stents on the U.S. market, such as stents sold by ACS, Boston Scientific, and Cordis. Based on the variety of

these competing stents, if Medtronic were to stop selling its stents in the United States, I would still have a sufficient selection of sizes and varieties of stents necessary to perform all desired procedures. Based on my personal experience, my review of medical literature, and my discussions with colleagues, moreover, Medtronic's stents are no safer or more effective than other stents on the market, such as those made by ACS, Boston Scientific, and Cordis. Accordingly, based on the variety of competing stents currently available, neither physicians nor patients will be harmed if Medtronic's infringing stents are taken off the market.

8. In my practice, I also use DES products, including Boston Scientific's Taxus stent and Cordis's Cypher stent

9. I understand that Medtronic has released a DES product, known as the "Endeavor," outside of the United States, and that it anticipates releasing the Endeavor in the U.S. this year. I understand that the Endeavor uses Medtronic's Driver stent as its platform

10. Based on my review of medical literature concerning the Endeavor and my experience with the Driver stent, I do not believe that the Endeavor would provide any significant additional medical benefit over the DES products currently on the market (i.e., Taxus and Cypher).

11. In an article published in December 2006, physicians performing clinical evaluations of the Endeavor described it as having "significantly higher angiographic late lumen loss" (i.e., restenosis) than Cordis's Cypher stent. Ex. 2 at 2447 [Kandzari et al, "Comparison of Zotarolimus-Eluting and Sirolimus-Eluting Stents in Patients With Native Coronary Artery Disease," *Circulation*, Vol. 48, No. 12, Dec. 19, 2006] This article also stated that "most other angiographic outcomes favored" the Cypher stent over the Endeavor stent. *Id.* Based on my



review of this article, the Endeavor may be somewhat inferior to, or at least no better than, the Cypher stent.

12 Another article, dated April 4, 2007, described the Endeavor stent as “equivalent to the sirolimus-eluting Cypher stent, in terms of clinical end points,” and stated that “target lesion revascularization (TLR) at two years were not statistically different for the two drug-eluting stents (DES), although fewer patients randomized to the Endeavor experienced periprocedural non-Q-wave MI, a difference that was maintained over the two years of follow-up ” Ex. 3 [Wood, “Two-year results from ENDEAVOR III point to safety, efficacy,” the heart.org, April 4, 2007]. While this article notes that the Endeavor study showed slightly lower rates of myocardial infarction compared to the Cypher, it also states that this is “a difference that might have been explained by the manner in which events were measured in the trial.” *Id* Additionally, as to this issue, the article noted that the study size was “relatively small” and that “sometimes you see statistical significance not biologically meaningful, but just due to the large confidence intervals of a small sample size ” *Id* This article also stated that “numerically TLRs [i.e., restenosis] were greater in the Endeavor stent-treated patients, while deaths were numerically lower.” *Id* On the subject of myocardial infarction rates between Endeavor and Cypher, however, the clinical results described in this article were inconclusive.

13 According to the April 4 article, Dr. Martin Leon, who presented the two-year results of the Endeavor III trial at the American College of Cardiology 2007 Scientific Sessions, explained that “the two-year results from Endeavor III alone do not add much to the stent-thrombosis debate, since rates of stent thrombosis per the trial’s definition were zero between both stents” (i.e., Endeavor and Cypher) *Id* Dr. Leon also stated that “there have been no reported stent thromboses” with the Endeavor, and that “we’re beginning to achieve a large-

enough sample size where our confidence about late stent thrombosis is increasing,” but that “[i]t’s by no means definitive: I’m anxious to see three-year follow-up from Endeavor II and whether these results continue to sustain themselves.” *Id*

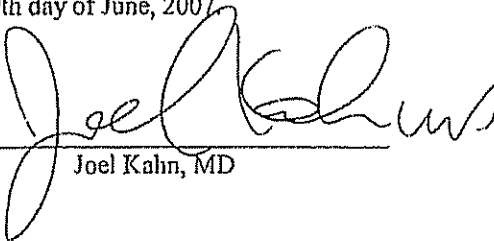
14. Based on my review of the April 4 article, the data on late-stent thrombosis for the Endeavor is inconclusive. While Medtronic’s Endeavor has not yet resulted in any reported cases of late-stent thrombosis, as Dr. Leon acknowledges, the results to date are “by no means definitive,” and we must wait for further results before drawing any conclusions on late-stent-thrombosis rates in the Endeavor.

15. I have not seen anything in the medical literature that suggests that the Endeavor would provide any significant additional medical benefit over the Cypher and Taxus stents, which are currently available in the United States. If anything, the literature suggests that the Endeavor may have a higher rate of restenosis, which is not desirable. As mentioned above, the study results comparing the rates of myocardial infarction and late-stent thrombosis between the Endeavor and the Cypher were inconclusive and thus not helpful.

06/29/2007 FRI 13:33 FAX 248 267 9076

002/002

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code. Executed on this the 29th day of June, 2007



Joel Kahn, MD

# Exhibit 1

## **JOEL K. KAHN, M.D., F.A.C.C., F.A.C.P., F.S.C.A.I.**

### ***Practice::***

#### **Address:**

Michigan Heart Group  
4600 Investment Drive, Suite 200  
Troy, MI 48098  
(248) 267-5050

### ***Education:***

1977-1980

University of Michigan, College of Literature,  
Science and Arts, Ann Arbor, Michigan

Bachelor of Science, Highest Distinction

1979-1983

University of Michigan Medical School,  
Ann Arbor, Michigan

Doctor of Medicine, Summa Cum Laude

### ***Professional Training:***

1983-1986

Resident, Department of Internal Medicine,  
University Hospital, Ann Arbor, Michigan.

1986-1989

Fellow, Division of Cardiology, University of  
Texas Southwestern Medical Center

1989-1990

Advanced Angioplasty Fellow, Mid-America Heart  
Institute of St. Luke's Hospital, Kansas City, MO

### ***Certification:***

Diplomate, American Board of Internal Medicine,  
1987; Subspecialty Boards, Cardiovascular  
Medicine, 1990; Subspecialty Boards, Interventional  
Cardiology, 2001; Nuclear Regulatory Commission,  
Nuclear Cardiology License, 1992. Diplomate,  
Certification Board of Nuclear Cardiology, 2003

### ***Academic Appointments:***

Clinical Assistant Professor of Medicine  
(Cardiology), Wayne State University School of  
Medicine, Detroit

### ***Administrative Appointments:***

Medical Director, Cardiac Rehabilitation, William  
Beaumont Hospital, Royal Oak, Michigan  
Medical Director, Carnegie Medical Institute, Troy,  
Michigan

### ***Hospital Affiliations:***

William Beaumont Hospital, Royal Oak and Troy,  
Michigan

***Professional Societies:***

American Medical Association, American College of Cardiology, American Heart Association, Society for Cardiac Angiography and Intervention, Michigan Medical Society, Oakland County Medical Society  
Fellow: American College of Cardiology, American College of Physicians, Society for Cardiac Angiography and Intervention

***Recent Awards:***

Top Docs, Cardiology, Hour Magazine, 2005

***Editorial Boards:***

Catheterization and Cardiovascular Intervention  
1993-2001  
Journal of Interventional Cardiology, 2000-present.

***PUBLICATIONS:***

1. **Kahn JK**, Menon KMJ. Evidence that arginine vasotocin inhibits human chorionic gonadotropin and cyclic 3'5' adenosine monophosphate stimulated ovarian steroidogenesis. *Biochem Biophys Res Commun*; 100:100-104, 1981.
2. **Kahn JK**, Kirsh MM. Infusion delivery time of the flow directed pulmonary artery catheter: clinical implications. *Heart and Lung*; 12:630-632, 1983.
3. **Kahn JK**, Zola B, Juni JE, Vinik AI. Radionuclide assessment of left ventricular diastolic filling in diabetes mellitus with and without cardiac autonomic neuropathy. *J Am Coll Cardiol* 7:1303-1309, 1986.
4. Zola B, **Kahn JK**, Juni JE, Vinik AI. Abnormal cardiac function in diabetic patients with autonomic neuropathy in the absence of ischemic heart disease. *J Clin Endocrinol Metab* 63:208-214, 1986.
5. **Kahn JK**, Zola B, Juni JE, Vinik AI. Decreased exercise heart rate and blood pressure response to exercise in patients with diabetes mellitus with autonomic neuropathy. *Diabetes Care* 9:389-394, 1986.
6. **Kahn JK**, Shenker Y, Grekin RG, Vinik AI. Plasma levels of immunoreactive atrial natriuretic hormone in patients with diabetes mellitus. *Regulatory Peptides* 15:323-332, 1986.
7. **Kahn JK**, Nifedipine associated acute psychosis. *Am J of Medicine* 81:705-706, 1986.
8. **Kahn JK**, Buda AJ. Long-term follow-up of coronary artery occlusion following blunt chest trauma. *Am Heart J* 113:207-210, 1987.
9. **Kahn JK**, Sisson JC, Vinik AI. QT interval prolongation and sudden death in diabetic autonomic neuropathy. *J Clin Endocrinol Metab* 64:751-754, 1987.
10. **Kahn JK**, Howell, JD. Profiles in Cardiology: Frank Norman Wilson, M.D. *Clin Cardiol* 10:616-618, 1987.
11. **Kahn JK**, Vinik AI. Exercise training in diabetes mellitus. *IM: Internal Medicine for the Specialist*. 9:117-125, 1988.
12. **Kahn JK**, Clinical correlates of supranormal left ventricular performance. *Am J Cardiol* 61:1145-1146, 1988.
13. **Kahn JK**, Sisson JC, Vinik, AI. Sudden cardiac death in diabetic autonomic neuropathy. *J Nuc Med* 29:1605-1606, 1988.

14. Henderson EB, **Kahn JK**, Corbett JR, Jansen DE, Pippin JJ, Kulkarni P, Ugolini V, Akers MS, Hansen C, Buja LM, Parkey RW, Willerson JT. Abnormal 1-123 metaiodobenzylguanidine myocardial washout and distribution may reflect myocardial adrenergic derangement in patients with congestive cardiomyopathy. *Circulation* 78:1192-1199, 1988.
15. **Kahn JK**, Carry MM, McGhie IM, Akers MS, Corbett JR. Quantitative lung thallium uptake during single photon computed emission tomography. *J Nucl Med* 30:288-294, 1989.
16. **Kahn JK**, Pippin JJ, Akers MS, Corbett JR. Estimation of jeopardized left ventricular myocardium in patients with silent and symptomatic ischemia as determined by 1-123 phenylpentadecanoic acid rotational tomography. *Am J Cardiol* 63:540-544, 1989.
17. **Kahn JK**, McGhie I, Akers MS, Sills MN, Pippin-JJ, Faber TL, Kulkarni PV, Willerson JT, Corbett JR. Quantitative rotational tomography with thallium-201 and technetium-99m 2-methoxy-isobutyl isonitrile: A direct comparison in normals and patients with coronary artery disease. *Circulation* 79:1282-1293, 1989.
18. **Kahn JK**, Hartzler GO. Saphenous vein graft angioplasty in a teenager. *Am J Cardiol* 65:259-260, 1990.
19. **Kahn JK**, Rutherford BD. Direct infarct angioplasty: Therapy for the 1990's. *J Invas Cardiol* 2:1-5, 1990.
20. **Kahn JK**, Hartzler GO. Retrieval of right heart fragments from implanted venous access catheters in patients with malignancy. *J Intervent Cardiol* 1989;2:199-202.
21. **Kahn JK**, Sills MN, Corbett JR, Willerson JT. The current role of nuclear cardiology in clinical medicine. *Chest* 1990;97:442-446.
22. **Kahn JK**, Rutherford BD, McConahay DR, Johnson WL, Giorgi LV, Hartzler GO. Short and long-term results of percutaneous transluminal coronary angioplasty in chronic dialysis patients. *Am Heart J* 1990;119:484-489.
23. **Kahn JK**, Rutherford BD, McConahay DR, Johnson WL, Giorgi LV, Hartzler GO. Supported "high-risk" coronary angioplasty using intra-aortic balloon pump counterpulsation. *J Am Coll Cardiol* 1990;15:1151-1155.
24. **Kahn JK**, Rutherford BD, McConahay DR, Johnson WL, Giorgi LV, Ligon R, Hartzler GO. Usefulness of angioplasty for acute myocardial infarction in patients with prior bypass grafting. *Am J Cardiol* 1990;65:698-702.
25. **Kahn JK**, Rutherford BD, Hartzler GO. Direct infarct angioplasty: Rationale and results. *CARDIO* 1990; March:102-106.
26. **Kahn JK**, Hartzler GO. Percutaneous thrombus aspiration in acute myocardial infarction. *Cath Cardiovasc Diagnosis* 1990;20:54-57.
27. **Kahn JK**, Hartzler GO. Retrograde coronary angioplasty of isolated arterial segments through saphenous vein grafts. *Cath Cardiovasc Diagnosis* 1990;20:88-93.
28. **Kahn JK**, Hartzler GO. The spectrum of coronary air embolism during coronary angioplasty: causes, consequences, and management. *Am Heart J* 1990;119:1374-1377.
29. **Kahn JK**, Rutherford BD, McConahay DR, Johnson WL, Giorgi LV, Hartzler GO. High dose contrast media administration during complex coronary angioplasty. *Am Heart J* 1990;120:533-536.
30. **Kahn JK**, and Hartzler GO. Retrieval of vein graft suture fragments with directional coronary atherectomy: a note of caution. *Am Heart J* 1990;120:692-696.

31. **Kahn JK**, Rutherford BD, Hartzler GO. Outcome following emergency surgery for failed elective balloon angioplasty in patients with prior coronary artery bypass surgery. *Am J Cardiol* 1990;66:285-288.
32. **Kahn JK**, Rutherford BD, McConahay DR, Johnson WL, Giorgi LV, Ligon R, Hartzler GO. Results of primary angioplasty for acute myocardial infarction in patients with multivessel coronary artery disease. *J Am Coll Cardiol* 1990;16:1089-1096.
33. **Kahn JK**, and Hartzler GO. Balloon rupture due to complex lesion morphology during coronary angioplasty. *Cath Cardiovasc Diagn* 1990;21:89-91.
34. **Kahn JK**, Rutherford BD, McConahay DR, Johnson WL, Giorgi LV, Shimshak TS, Hartzler GO. Early postoperative balloon coronary angioplasty for failed coronary artery bypass grafting. *Am J Cardiol* 1990;66:943-946.
35. **Kahn JK**, Rutherford BD, McConahay DR, Johnson WL, Giorgi LV, Hartzler GO. Catheterization lab events during direct infarct angioplasty: a contemporary analysis. *Circulation* 1990;82:1910-1915.
36. **Kahn JK**, Rutherford BD, McConahay DR, Johnson WL, Giorgi LV, Hartzler GO. Timing and mechanism of in-hospital and late death following primary coronary angioplasty during acute myocardial infarction. *Am J Cardiol* 1990;66:1045-1048.
37. **Kahn JK**, Hartzler GO. Frequency and causes of failure with contemporary balloon coronary angioplasty and implications for new technologies. *Am J Cardiol* 1990;66:858-860.
38. **Kahn JK**, Rutherford, McConahay, Hartzler GO. Inflation pressure requirements for coronary angioplasty. *Cath Cardiovasc Diagn* 1990;24:144-147.
39. **Kahn JK**, Hartzler GO. Evidence for dynamic coronary vasoconstriction in the early minutes of acute myocardial infarction. *Am Heart J* 1991;121:188-190.
40. Eichorn EJ, Grayburn PA, Willard JE, Anderson HV, Bedotto JB, Carry M., **Kahn JK**, Willerson JT. Cyclic coronary artery flow variations before and after percutaneous transluminal coronary angioplasty in man. *J Am Coll Cardiol*;17:43-52.
41. Stevens T, **Kahn JK**, Ligon RW, Spaude S, Rutherford BD, McConahay DR, Johnson WL, Giorgi LV, Shimshak TM, Hartzler GO, McCallister BD. Safety and efficacy of PTCA in patients with left ventricular dysfunction. *Am J Cardiol* 1991;68:313-319.
42. **Kahn JK**, Current advances in the noninvasive detection of coronary artery disease. *Postgraduate medicine* 1991;89:149-158.
43. **Kahn JK**, Outpatient management of progressive congestive heart failure. *Postgraduate Medicine* 1991;89:102-107.
44. **Kahn JK**, High risk coronary angioplasty. *CARDIO* 1991;April:46-56.
45. **Kahn JK**, Intraaortic balloon pumping in percutaneous transluminal coronary angioplasty. *Cardiac Assists* 1991;6:1-4.
46. **Kahn JK**, Caring for patients after coronary intervention. *Postgraduate Medicine* 1992;91:415-427.
47. **Kahn JK**, Coronary angioplasty for acute myocardial infarction. *Primary Cardiology* 1992;18:22-28.
48. **Kahn JK**, Rutherford BD, McConahay DR, Johnson WL, Giorgi LV, Shimshak TS, Ligon R, Hartzler GO. Comparison of the procedural results and risks of coronary angioplasty in men and women for conditions other than acute myocardial infarction. *Am J Cardiol* 1992;69:1241-2.



49. Pippin JJ, Jansen DE, Henderson EB, Hansen CL, Ugolini V, **Kahn JK**, Kulkarni PV, Corbett JR. Myocardial fatty acid utilization at various workloads in normal volunteers: Iodine-123 phenylpentadecanoic acid and single photon emission computed tomography to investigate myocardial metabolism. *Am J Card Imaging* 1992;6:99-108.
50. **Kahn JK**, Percutaneous transluminal coronary angioplasty through an anomalous left main coronary artery. *Am Heart J* 1992;124:1372-1374.
51. **Kahn JK**, Inadvertent thrombolytic therapy for cardiovascular conditions masquerading as acute myocardial infarction. *Clin Cardiol* 1993;16:67-71.
52. **Kahn JK**, Balloon catheter requirements during contemporary percutaneous transluminal coronary angioplasty. *Cathet Cardiovasc Diagn* 1992;27:179-82.
53. **Kahn JK**, Slow coronary flow complicating coronary angioplasty in post-thrombolytic patients. *Cor Artery Dis* 1993;4:61-65.
54. **Kahn JK**, Angioplasty after CABG surgery, *CARDIO Interventions* 1992;2:25-31.
55. **Kahn JK**, Anticoagulant therapy for atrial fibrillation. Recommendations from major studies. *Postgraduate Medicine* 1992;92:119-130.
56. **Kahn JK**, Care of the patient after coronary bypass surgery. *Postgraduate Medicine* 1993;93:249-262.
57. **Kahn JK**, Hartzler GO. Management of refractory hypotension during coronary angioplasty with intracoronary epinephrine. *Am Heart J* 1993;126:463-6.
58. Bedetto JB, **Kahn JK**, Rutherford BD, McConahay DR, Ligon RW, Hartzler GO. Failed direct coronary angioplasty for acute myocardial infarction: In-hospital outcome and predictors of death. *J Am Coll Cardiol* 1993;22:690-4.
59. **Kahn JK**, Rutherford BD, McConahay DR, Ligon RW, Hartzler GO. Acute and long-term outcome of 83 patients after balloon angioplasty of totally occluded bypass grafts. *J Am Coll Cardiol* 1994;23:1038-42.
60. **Kahn JK**, In praise of balloon coronary angioplasty (Editorial). *Newsletter, Michigan Chapter of the American College of Cardiology.* 1992;3:7-9.
61. **Kahn JK**, Bernstein M., Bengtson JR. Isolated Right Ventricular Myocardial Infarction. *Ann Intern Med* 1993;118:708-11.
62. **Kahn JK**, Fischer JC. Rapid Development of Left Main Disease After Coronary Artery Bypass Grafting for Failed Angioplasty: A Rare Cause of Postoperative Angina. *Cathet Cardiovasc Diagn* 1993;29:221-3.
63. **Kahn JK**, Angiographic suitability for catheter revascularization of total coronary occlusions in patients from a community hospital setting. *Am Heart J* 1993;126:561-4.
64. **Kahn JK**, Rutherford BD, McConahay DR, Johnson WL, Giorgi LV, Ligon RW, Hartzler GO. Clinical and angiographic correlates of in-hospital death following coronary angioplasty for conditions other than acute myocardial infarction. *Am J Cardiol* 1993;72:826-7.
65. **Kahn JK**, Cragg DR, Almany SL, Ajluni S. Aggressive therapy of acute myocardial infarction. *Postgraduate Medicine* 1993;94:51-67.
66. **Kahn JK**, Angiographic eligibility of community hospital patients with multivessel coronary artery disease for PTCA or coronary artery bypass grafting. *Am J Cardiol* 1993;72:460-463.
67. **Kahn JK**, Kodali U, Savas V, Gordon R. Effects of chronic warfarin therapy on complications of coronary angioplasty during acute myocardial infarction with coronary

angioplasty. *Am J Cardiol* 1995;75:724.

**68. Kahn JK**, PTCA of the left main coronary artery: Opening pandora's box? *Cathet Cardiovasc Diagn* 1994;33:108-9.

**69. Kahn JK**, Collateral injury by total occlusion angioplasty: biting the hand that feeds us: *Cathet Cardiovasc Diagn* 1995;34:65-6.

**70. Kahn JK**, Stenting for acute myocardial infarction: opening the open artery hypothesis wider. *Cathet Cardiovasc Diagn* 1995;34:147-8.

**71. Kahn JK**, Guide catheter exchange device: one small step for man. *Cathet Cardiovasc Diagn* 1994;33:288.

**72. Kahn JK**, Glazier S., Swor R, Savas V, O'Neill WW. Primary coronary angioplasty for acute myocardial infarction complicated by out of hospital cardiac arrest. *Am J Cardiol* 1995;75:1069-70.

**73. Kahn JK**, Reversing coronary atherosclerosis. *Postgraduate Medicine*. 1993;94:50-65.

**74. Kahn JK**, Central venous catheters: Placement and monitoring tips. *Postgraduate Medicine* 1995;97:65-68.

**75. Franklin B, Kahn JK**, Detecting the individual prone to exercise related sudden cardiac death. *Sports Science Rev* 1995;4:85-105.

**76. Kahn JK**. Why we get out of bed to infarct PTCA. *Cathet Cardiovasc Diagn* 1996;39:340.

**77. Kahn JK**, Is PTCA of saphenous vein bypass grafts still OK? *Cathet Cardiovasc Diagn* 1995;34:300.

**78. Kahn JK**, Dynamic coronary vasoconstriction in arteries not involved with acute myocardial infarction. *Cathet Cardiovasc Diagn* 1995;36:371-3.

**79. Safian RD, Hoffman MA, Almany SA, Kahn JK, Reddy V, Marselese D, Gangadharan V, Ajluni S, Friedman HZ, Schrieber TL..** Comparison of coronary angioplasty with compliant and noncompliant balloons (The Angioplasty Compliance Trial). *Am J Cardiol* 1995;76:518-20.

**80. O'Keefe JH, Stone GW, McAllister BD, McCallister BD, Maddex C, Ligon R, Kacich RL, Kahn JK, Caverio P, Hartzler GO, McCallister BD.** Combination Lovastatin and probucol for the prevention of restenosis after coronary angioplasty. *Am J Cardiol* 1996;77:649-52

**81. Kahn JK**, Can we defend the Bill of Rights? *Cathet Cardiovasc Diagn* 1996;37:131.

**82. Kahn JK**, To air is human, to prevent is divine. *Cathet Cardiovasc Diagn* 1995;36:319

**83. Kahn JK**, Are percutaneous coronary interventions sterile or sterile-lies? *Cathet Cardiovasc Diagn* 1995;36:10.

**84. Kahn JK**, Death following direct infarct angioplasty: Lessons that we've learned. *Cathet Cardiovasc Diagn* 1995;35:197.

**85. Kahn JK**. Maximizing your guide-given talents. *Cathet Cardiovasc Diagn* 1996;37:434.

**86. Almany SL, Mileto L, Kahn JK.** Preoperative cardiac evaluation. Assessing risk before noncardiac surgery. *Postgraduate Med* 1995;98:171-182.

**87. Kahn JK**. Friction free stenting. *Cathet Cardiovasc Diagn* 1997;41:20.

**88. Kahn JK**. Infarct artery stents: the first year. *Cathet Cardiovasc Diagn* 1997;40:342.

- 89. Kahn JK.** Confusion about perfusion. *Cathet Cardiovasc Diagn* 1997;40:186.
- 90. Kahn JK.** Infarct angioplasty: the hole story. *Cathet Cardiovasc Diagn* 1997;42:157.
- 91. Kahn JK, Almany SL.** No-reflow no more? *Cathet Cardiovasc Diagn* 1996;39:119.
- 92. Rabah MM, Kahn JK.** How does the fairer sex fare after PTCA. *Cathet Cardiovasc Diagn* 1996;39:16.
- 93. Kahn JK.** Culprit vessel angioplasty: it's a small world after all. *Cathet Cardiovasc Diagn* 1996;37:262.
- 94. Bowers TR, Kahn JK.** There's no business like flow business. *Cathet Cardiovasc Diagn* 1996;38:255.
- 95. Thompson RJ, McCullough PA, Kahn JK, O'Neill WW.** Prediction of death and neurologic outcome in the emergency department in out-of-hospital cardiac arrest survivors. *Am J Cardiol* 1998;81:17-21.
- 96. Thompson RJ, McCullough PA, Kahn JK, O'Neill WW.** A simple scoring system to predict clinical outcome after resuscitation from cardiac arrest. *J Critical Illness* 1998;13:298-300.
- 97. McCullough PA, Thompson RJ, Tobin KJ, Kahn JK, O'Neill WW.** Validation of a decision support tool for the evaluation of cardiac arrest victims. *Clin Cardiol* 1998;21:195-200.
- 98. Kahn JK.** Two stents are better than one? *Cathet Cardiovasc Diagn* 1998;44:441.
- 99. Kahn JK.** Stents in smaller arteries: a big deal. *Cathet Cardiovasc Diagn* 1998;45:239.
- 100. Kahn JK.** Coronary stents: Increasing options and indications. *Cathet Cardiovasc Diagn* 1998;45:375.
- 101. Kahn, JK.** Options to heparin anticoagulation in interventional cardiology. *Cathet Cardiovasc Intervent.* 1999 ;46:356.
- 102. den Heijer P, Vermeer, F, Ambrosioni E, Sadowski Z et al. (Participating Clinical Investigator).** Evaluation of a weight-adjusted single-bolus plasminogen activator in patients with myocardial infarction. A double-blinded, randomized angiographic trial of lanoteplase versus alteplase. *Circulation* 1998;98:2117-2125.
- 103. Kahn JK.** Reperfusion therapy for every infarction with ST segment elevation. *Cathet Cardiovasc Intervent* 1999;46:134.
- 104. Kahn JK.** How to repair an aortic tear. *Cathet Cardiovasc Intervent* 2000;49:90.
- 105. Kahn JK.** Catheter debris: It's a jungle in there. *Cathet Cardiovasc Intervent* 2000;49:395.
- 106. Kahn JK.** No reflow? No way! *Cathet Cardiovasc Intervent* 2000;51:32.
- 107. Valez CA, Kahn JK.** Compartment syndrome from balloon pump. *Cathet Cardiovasc Intervent* 2000;51:217-219.
- 108. Kahn, JK.** Stents for infarcts: the missing link? *Cathet Cardiovas Intervent* 2000;51:280.
- 109. Dunning DW, Kahn JK, Hawkins ET, O'Neill WW.** Iatrogenic coronary artery dissections extending into and involving the aortic root. *Cathet Cardiovasc Intervent* 2000;51:387-393.
- 110. Kahn JK.** Femoral closure devices: seal of approval. *Cathet Cardiovasc Intervent* 2001;52:8.
- 111. Kahn JK, O'Neill WW.** Two vessels or not two vessels. That is the question. *Am Heart J* 2002;143:948-9.

112. Skelding KA, Mehta LS, Pica MC, Fointa B, Shoukfeh M, Grines C, O'Neill WW, **Kahn JK**. Primary percutaneous interventions for acute myocardial infarction in octogenarians: A single-center experience. *Clin Cardiol* 2002 25:363-6.
113. Dunning DS, **Kahn JK**, O'Neill WW. The Long-term Consequences of Lost Intracoronary Stents. *J Intervent Cardiol* 2002;15:345-8.
114. Fejka M, Dixon SR, Safian RD, O'Neill WW, Grines CL, Finta B, Marcovitz PA, **Kahn JK**. Cardiac tamponade complicating percutaneous coronary intervention: diagnosis, management and clinical outcome. *Am J Cardiol* 2002;90:1183-6.
115. Stone GW, Grines CL, Cox DA, Garcia E, Tchong JE, Griffin JJ, Guagliumi G, Stuckey T, Turco M, Carroll JD, Rutherford BD, Lansky AJ and **CADILLAC Investigators**. Comparison of angioplasty with stenting with or without abciximab in acute myocardial infarction. *N Engl J Med* 2002 346:957-66.
116. **Kahn, JK**. Geoffrey O. Hartzler, MD. *Clinical Cardiology* 2004;27:58-9.
117. **Kahn JK**. Statin therapy of dyslipidemias: A viewpoint on safety and efficacy. *Am J Med and Sports* 2004;6:37-8.
118. Ochoa A, Pellizon G, Addala S, Boura J, Grines C, Isayenko Y, Boura J, Rempisnki D, O'Neill W, **Kahn J**. Abbreviated dosing of n-acetylcysteine prevents contrast induced nephropathy after elective and urgent coronary angiography and intervention. *J Intervent Cardiol* 2004;17;1-7.
119. West AJ, Dixon SR, **Kahn JK**, Levin RN, O'Neill WW, Grines CL, Berman AD. Effectiveness of Primary Angioplasty for Acute Myocardial Infarction in Patients on dialysis. *Am J Cardiol* 2004;93:468-470.
120. Dukupati S, O'Neill WW, Harjai KJ, Sanders W, Boura JA, Bartholomew BA, Yerkey MW, Chanamolu S, Sadeghi HM, **Kahn JK**. Characteristics of cerebrovascular accidents after percutaneous coronary interventions. *J Am Coll Cardiol* 2004;43:1161-7.
121. Fejka M, **Kahn JK**. Diagnosis, management, and clinical outcome of cardiac tamponade complicating percutaneous coronary interventions. *Cardiovascular Reviews and Reports* 2003;24:416-20.
122. Ballantyne CM, Blazing MA, Hunninghake DB, Davidson MH, Yuan Z, DeLucca P, Ramsey KE, Hustad CM, Palmisano J, CHESS study Group (**Kahn JK**). Effect on high density lipoprotein cholesterol of maximum dose simvastatin and atorvastatin in patients with hypercholesterolemia: Results of the Comparative HDL Efficacy and Safety Study (CHESS). *Am Heart J* 2003;146:862-9.
123. Franklin BA, de Jong A, **Kahn JK**, McCullough PA. Fitness and mortality in the primary and secondary prevention of coronary artery disease: Does the effort justify the outcome? *Am J Med Sports* 2004;6:23-27.
124. Franklin BA, **Kahn JK**, Gordon NF, Bonow RO. Comprehensive lifestyle modification: The proven Polypill. *Am J Cardiol* 2004;94:162-166.
125. Addala S, Grines CL, Dixon SR, Stone GW, Boura JA, Ochoa AB, Pellizzon G, O'Neill WW, **Kahn JK**. Predicting mortality in patients with ST-elevation myocardial infarction treated with primary percutaneous coronary intervention (PAMI risk score). *Am J Cardiol* 2004;93:629-32.
126. Gallagher MJ, Dixon SR, Madala M, Rimar SD, O'Neill WW, Kahn JK. Percutaneous transfemoral coronary and peripheral procedures via aortofemoral synthetic vascular grafts: a review of 123 diagnostic and interventional cases. *Am J Cardiol* 2005;96:382-5.

127. Vijayaraghavan K, Santora L, **Kahn JK**, Abbott N, Torelli J, Vardi G. New graduated pressure regimen for external counterpulsation reduces mortality and improves outcomes in congestive heart failure. A report from the Cardiomedics External Counterpulsation Patient Registry. *Congestive Heart Failure* 2005;11:147-152.
- 128 Mattichak SJ, Reed PS, Gallagher MJ, Boura JA, O'Neill WW, **Kahn JK**. Evaluation of the safety of warfarin, in combination with antiplatelet therapy, for patients treated with coronary stents for acute myocardial infarction. *J Intervent Cardiol* 2005;18:163-6.
129. Gallagher MJ, Franklin B, Ehrman JE, Keteyan SJ, Brawner C, **Kahn JK**, Sandberg KR, DeJong A, Mattichak SJ, McCullough PA. Comparative impact of obesity and heart failure on measures of cardiorespiratory fitness. *Chest* 2005 (in press).
130. Harjai KJ, Berman AD, Grines CL, **Kahn J**, Marsalese D, Mehta RH, Schreiber T, Boura JA, O'Neill WW. Impact of interventionalist volume, experience, and board certification on coronary angioplasty outcomes in the era of stenting. *Am J Cardiol* 2004;94:421-6.
131. Addala S, **Kahn JK**, Moccia TF, Harjai K, Pellizon G, Ochoa A, O'Neill WW. Outcome of ventricular fibrillation developing during percutaneous coronary interventions in 19,497 patients without cardiogenic shock. *Am J Cardiol* 2005;96:764-5.
132. Dutcher JR, **Kahn JK**, Grines CL, Franklin B. Comparison of left ventricular ejection fraction and exercise capacity as predictors of two- and five- year mortality following acute myocardial infarction. *Am J Cardiol*. 2007;99:436-41.
133. Reed PS, **Kahn JK**, Dixon SR, Boura JA, O'Neill WW. Gadodiamide versus iodinated contrast in the prevention of contrast-induced nephropathy in patients with chronic kidney disease undergoing coronary angiography or intervention. *Am J Cardiol* (in press).
134. Chinnaiyan KM, Trivax J, Franklin BA, Williamson B, **Kahn JK**. Stress testing in patients with implantable cardioverter-defibrillators: a preliminary report. *Preventive Cardiol* 2007;10:92-95.

#### **BOOK CHAPTERS:**

1. Corbett JR, **Kahn JK**, Parkey RW. Cardiac SPECT: Assessment of myocardial perfusion and function. in *PET/SPECT: Instrumentation, radiopharmaceuticals, and physiologic measurement*. American College of Nuclear Physicians, 1988. pp153-173.
2. Faber TL, Stokely EM, **Kahn JK**, Corbett JR. Automatic determination of 3-dimensional left ventricular endo- and epicardial surfaces in gated perfusion tomograms. *Proceedings of the 9th Conference on Computer Applications in Radiology*. May, 1988. pp 120-126.
3. **Kahn JK**, Pippin JJ, Corbett JR. New myocardial imaging agents: Description and applications in: Wolfe C. (Editor). *Cardiac Imaging*. Saunders, 1989, 589-605.
4. Corbett JR, **Kahn JK**, Parkey R, Buja LM, Willerson JT. Single photon emission computed tomography for the detection and sizing acute myocardial infarcts with technetium stannous pyrophosphate and the detection of altered myocardial metabolism with iodine-123 phenylpentadecanoic acid. In: Pohost GM and O'Rourke RA. . *Cardiovascular Imaging*. Little Brown. 1991. 261-274.
5. **Kahn JK**, Hartzler GO. Coronary angioplasty for acute and evolving myocardial infarction. In: Clark D. (Editor). *Coronary Angioplasty*. AR Liss, 1991:pgs. 73-81.

6. **Kahn JK**, Hartzler GO. PTCA in patients with poor left ventricular function. in Ellis SG, Editor. Williams and Wilkins. 1996.469-474.
7. **Kahn JK**, O'Neill WO. PTCA in acute myocardial infarction. In Ellis SG, Editor. Williams and Wilkins. 1996. 558-564.
8. **Kahn JK**, O'Neill WO. Direct Angioplasty for acute myocardial infarction. In Serruys P, Editor. Textbook of Cardiovascular Interventions. (in press 1994).
9. **Kahn JK** and Almany SL, Supported angioplasty. In Grech ED, Editor. Practical Interventional Cardiology. Dunitz. 1997. 233-248.
10. **Kahn JK**, PTCA in special patient subsets. In Freed M. Grines C, Editors. Manual of Interventional Cardiology, Physicians Press, 1996 pgs. 175-182.
11. **Kahn JK**, Howell JD. Frank Norman Wilson. In Hurst JW, Conti CR, Fye B, Editors. Profiles in Cardiology. Foundation for Advances in Medicine and Science. 2003. pgs 246-7.

#### **MONOGRAPHS:**

1. **Kahn JK**, Intra-aortic balloon pumping: theory and applications. A monograph for the clinician. Communications Media for Education, Inc. 1991:1-20.
2. **Kahn JK**. Intra-aortic balloon pumping: Theory and clinical applications in the 21<sup>st</sup> Century. 2004:1-20.

#### **Video National Course Presentation**

1. **Kahn JK**. Elective and Emergency Cardiac Interventions. 2004-2005 Medical-Dental-Legal Update, American Education Institute, Inc, Birmingham, MI.



## Exhibit 2

# Comparison of Zotarolimus-Eluting and Sirolimus-Eluting Stents in Patients With Native Coronary Artery Disease

## A Randomized Controlled Trial

David E. Kandzari, MD, FACC,\* Martin B. Leon, MD, FACC,† Jeffrey J. Popma, MD, FACC,§ Peter J. Fitzgerald, MD, FACC,|| Charles O'Shaughnessy, MD, FACC,# Michael W. Ball, MD, FACC,\*\* Mark Turco, MD, FACC,†† Robert J. Applegate, MD, FACC,† Paul A. Gurbel, MD, FACC,‡‡ Mark G. Midei, MD, FACC,§§ Sejal S. Badre, MS,§ Laura Mauri, MD, MSc, FACC,§ Kweli P. Thompson, MD,¶ LeRoy A. LeNarz, MD,¶ Richard E. Kuntz, MD, FACC,¶ for the ENDEAVOR III Investigators

*Durham and Winston-Salem, North Carolina; New York, New York; Boston, Massachusetts; Palo Alto and Santa Rosa, California; Elyria, Ohio; Indianapolis, Indiana; and Takoma Park, Baltimore, and Towson, Maryland*

<b>OBJECTIVES</b>	This trial examined the relative clinical efficacy, angiographic outcomes, and safety of zotarolimus-eluting coronary stents (ZES) with a phosphorylcholine polymer versus sirolimus-eluting stents (SES).
<b>BACKGROUND</b>	Whether a cobalt-based alloy stent coated with the novel antiproliferative agent, zotarolimus, and a phosphorylcholine polymer may provide similar angiographic and clinical benefit compared with SES is undetermined.
<b>METHODS</b>	A prospective, multicenter, 3:1 randomized trial was conducted to evaluate the safety and efficacy of ZES (n = 323) relative to SES (n = 113) in 436 patients undergoing elective percutaneous revascularization of de novo native coronary lesions with reference vessel diameters between 2.5 mm and 3.5 mm and lesion length $\geq 14$ mm and $\leq 27$ mm. The primary end point was 8-month angiographic in-segment late lumen loss.
<b>RESULTS</b>	Angiographic in-segment late lumen loss was significantly higher among patients treated with ZES compared with SES ( $0.34 \pm 0.44$ mm vs. $0.13 \pm 0.32$ mm, respectively; $p < 0.001$ ). In-hospital major adverse cardiac events were significantly lower among patients treated with ZES (0.6% vs. 3.5%, $p = 0.04$ ). In-segment binary angiographic restenosis was also higher in the ZES cohort (11.7% vs. 4.3%, $p = 0.04$ ). Total (clinically and non-clinically driven) target lesion revascularization rates at 9 months were 9.8% and 3.5% for the ZES and SES groups, respectively ( $p = 0.04$ ). However, neither clinically driven target lesion revascularization (6.3% zotarolimus vs. 3.5% sirolimus, $p = 0.34$ ) nor target vessel failure (12.0% zotarolimus vs. 11.5% sirolimus, $p = 1.0$ ) differed significantly.
<b>CONCLUSIONS</b>	Compared with SES, treatment with a phosphorylcholine polymer-based ZES is associated with significantly higher late lumen loss and binary restenosis at 8-month angiographic follow-up. (The Endeavor III CR; <a href="http://clinicaltrials.gov/ct/show/NCT00265668?order=1">http://clinicaltrials.gov/ct/show/NCT00265668?order=1</a> ) (J Am Coll Cardiol 2006;48:2440–7) © 2006 by the American College of Cardiology Foundation

Compared with bare metal coronary stents, the beneficial treatment with drug-eluting stents to avoid restenosis and the need for repeat revascularization has been consistently demonstrated in systematic, randomized clinical trials (1–8) and observational studies (9–11) that have included both selected and broad patient populations with varying clinical and angiographic characteristics. Because of their efficacy in limiting neointimal hyperplasia after percutaneous coronary

revascularization, drug-eluting stents have become routine therapy in clinical practice, and currently available paclitaxel-eluting stents and sirolimus-eluting stents (SES) have become the comparative standard for evaluation of novel anti-proliferative therapies and stent technologies.

Whether safety, clinical efficacy, and angiographic outcomes are similar between differing drug-eluting stents has only been recently examined (12–18). An important emerging controversy in clinical trials comparing drug-eluting stent therapies has been the relationship of clinical end points such as target lesion revascularization or target vessel failure (generally considered the “gold standards” for assessing safety and efficacy) and surrogate angiographic end points such as late lumen loss, which measure more precisely the biological effects of these novel anti-restenosis therapies on intimal hyperplasia (19,20).

Zotarolimus (ABT-578, Abbott Pharmaceuticals, Abbott Park, Illinois) is a novel pharmacologic therapy with both

From the \*Duke Clinical Research Institute, Durham, North Carolina; †Baptist Medical Center and Wake Forest University, Winston-Salem, North Carolina; ‡Columbia University Medical Center and the Cardiovascular Research Foundation, New York, New York; §Harvard Clinical Research Institute and Brigham and Women's Hospital, Boston, Massachusetts; ||Stanford University Medical Center, Palo Alto, California; ¶Medtronic, Inc., Santa Rosa, California; #North Ohio Heart Center, Elyria, Ohio; \*\*St. Vincent's Hospital, Indianapolis, Indiana; ††Washington Adventist Hospital, Takoma Park, Maryland; ‡‡Sinai Center for Thrombosis Research, Baltimore, Maryland; and §§St. Joseph's Medical Center, Towson, Maryland. Study support provided by Medtronic Vascular, Inc. Santa Rosa, California.

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**Abbreviations and Acronyms**

CK	= creatine kinase
IVUS	= intravascular ultrasound
MACE	= major adverse cardiac events
MLD	= minimal lumen diameter
SES	= sirolimus-eluting stent
ZES	= zotarolimus-eluting stent

anti-proliferative and anti-inflammatory effects. A tetrazole-containing macrocyclic immunosuppressant, zotarolimus shares structural homology and biological activity with the anti-restenotic agent sirolimus. Recently, in a randomized trial comparing coronary revascularization with zotarolimus-eluting (ZES) and bare metal stents, treatment with ZES was associated with significant reductions in angiographic restenosis and repeat target lesion revascularization (8). Despite this marked benefit relative to conventional bare metal stents, the comparative efficacy between ZES and other effective drug-eluting stents, such as SES, is undetermined. We therefore performed a randomized, multicenter trial to examine the relative safety, clinical efficacy, and angiographic outcomes of a phosphorylcholine polymer-based coronary stent eluting zotarolimus versus sirolimus in patients with native coronary lesions.

**METHODS**

**Trial overview and study population.** The ENDEAVOR III (A Randomized Controlled Trial of the Medtronic Endeavor Drug [ABT-578] Eluting Coronary Stent System Versus the Cypher Sirolimus-Eluting Coronary Stent System in De Novo Native Coronary Artery Lesions) trial was a prospective, randomized, single-blinded multicenter trial comparing ZES and SES in elective percutaneous coronary revascularization at 29 hospitals in the U.S. Individuals eligible for enrollment were consecutive patients age 18 years or older with symptomatic ischemic heart disease due to de novo stenotic lesions (>50% angiographic diameter stenosis by visual estimate) in native coronary arteries. Angiographic inclusion criteria were a reference vessel diameter between 2.5 mm and 3.5 mm and lesion length  $\geq 14$  mm and  $\leq 27$  mm. Patients were excluded if they experienced recent (<72 h) myocardial infarction, underwent prior stent placement within the target vessel or any other vessel within 30 days of the index procedure, or had any general contraindication to the revascularization procedure and routine pharmacologic therapies. Principal angiographic exclusion criteria were a left ventricular ejection fraction <30%, stenosis >40% elsewhere in the target vessel (other than the target lesion), involvement of a sidebranch  $\geq 2.0$  mm in diameter, unprotected left main coronary disease, chronic total occlusions, and Thrombolysis In Myocardial Infarction flow grade <2 in the treatment vessel. The study was approved by the institutional review board at each enrolling site, and consecutive, eligible pa-

tients signed written informed consent before the interventional procedure.

**Device description.** The Endeavor drug-eluting coronary stent (Medtronic Vascular, Inc., Santa Rosa, California) is a cobalt-based alloy stent with a phosphorylcholine polymer (21) and zotarolimus dose concentration of 10  $\mu\text{g}/\text{mm}$  stent length. In a porcine coronary model, stents coated with a phosphorylcholine polymer and zotarolimus were associated with significant reductions in neointimal area and percent area stenosis (22). In a similar preclinical study, approximately 95% of zotarolimus is eluted from the stent within 15 days of implantation, although drug concentrations within surrounding vascular tissue may be detected as late as 30 days after stent deployment (23). Zotarolimus-eluting stents were available in diameters ranging from 2.5 mm to 3.5 mm and in lengths from 9 mm to 30 mm. The control SES stent (Cypher, Cordis Corporation, Miami Lakes, Florida) was available in diameters ranging from 2.5 mm to 3.5 mm and in lengths from 8 mm to 33 mm.

**Randomization, interventional procedure, and adjunctive drug therapies.** Patients were blinded to treatment assignment and randomized to the ZES or SES in a 3:1 fashion. Revascularization was to be performed with no more than 1 study stent except in instances of insufficient lesion coverage or as a "bailout" procedure for dissection or thrombus. All lesions were pre-dilated with balloon angioplasty, and the protocol specified that stent length should be 3 to 5 mm longer than the lesion for adequate coverage. Both the ZES and SES were expanded to achieve <10% residual stenosis by visual estimate in the treated segment, with a combination of the stent deployment balloon and, at the operator's discretion, subsequent post-dilatation balloons. After stent implantation was optimized by angiographic criteria, routine intravascular ultrasound (IVUS) of the target lesion was performed.

Before revascularization, all patients received treatment with aspirin (325 mg/day) and clopidogrel (75 mg/day) for at least 48 h, followed by dual antiplatelet therapy for a minimum of 3 months after the procedure and indefinite aspirin therapy. In those patients not receiving at least 48 h of dual anti-platelet therapy before the procedure, a loading dose of clopidogrel (300 to 600 mg) was given immediately before or during the procedure. Unfractionated heparin was administered to achieve an activated clotting time  $\geq 250$  s or 200 to 250 s if an intravenous glycoprotein IIb/IIIa inhibitor was used. Treatment with additional device therapies (e.g., atherectomy) was not permitted.

Clinical events were assessed during hospital stay and at clinic visits at 30 days and at 9 months after the index procedure. All patients were scheduled to undergo follow-up angiography and IVUS at 8 months or sooner if the patient developed angina or objective evidence of target vessel ischemia.

**Data management and core laboratories.** All data were submitted to a central data coordinating facility (Cardiovascular Data Analysis Center, Harvard Clinical Research

Institute, Harvard Medical School, Boston, Massachusetts). Coronary angiograms performed at baseline and at follow-up were reviewed by an independent angiographic core laboratory (Brigham and Women's Angiographic Core Laboratory, Boston, Massachusetts). Standard image acquisition was performed with 2 or more angiographic projections of the stenosis before and after stent placement. Compulsory angiography was planned  $240 \pm 30$  days after the procedure with identical angiographic projections. Qualitative analysis was performed with the modified American College of Cardiology (ACC)/American Heart Association (AHA) classification (24). Quantitative angiographic analysis was performed with a validated automated edge detection algorithm (Medis CMS, Leiden, the Netherlands) (25). Frames were selected for analysis in the 2 "sharpest and tightest" views that minimized foreshortening and vessel overlap. The contrast-filled injection catheter was used as the calibration source. A 5- to 10-mm segment of reference diameter proximal and distal to the stenosis was used to calculate the average reference vessel diameter at baseline, after stent implantation, and at follow-up. Similarly, IVUS images were examined by an independent core laboratory (Cardiovascular Core Analysis Laboratory, Stanford University, Stanford, California) (26,27). Reviewers from each core laboratory were unaware of the type of stent implanted. For both coronary angiograms and IVUS images, quantitative analysis was performed to evaluate the in-stent region (bordered by the stent margins) as well as the in-segment region (in-stent region plus 5-mm margins proximal and distal to the stent).

**Study end points and definitions.** The primary end point of in-segment late lumen loss was examined by quantitative coronary angiography at 8-month angiographic follow-up. Late lumen loss was defined as the difference between the in-segment minimal lumen diameter (MLD) at the completion of the stenting procedure and the in-segment MLD measured at angiographic follow-up.

Secondary clinical safety and efficacy end points included major adverse cardiac events (MACE: all-cause death, myocardial infarction, and clinically driven target lesion revascularization); the individual components of the composite end point in-hospital, at 30 days, and at 9 months; stent thrombosis (acute, <1 day; subacute, 1 to 30 days; and late, >30 days); clinically driven target vessel revascularization at 9 months; and target vessel failure (cardiovascular death, myocardial infarction, and clinically driven target vessel revascularization) at 9 months. Device success was defined as a <50% diameter stenosis of the target lesion (determined by the core angiographic laboratory) with the assigned study stent, and procedure success was defined as device success and no in-hospital MACEs. Myocardial infarction was defined as a creatine kinase (CK) elevation  $\geq 2$  times above the upper limit of normal with any associated elevation in the CK myocardial band or the development of new pathologic Q waves in 2 contiguous electrocardiographic leads. Clinically driven revasculariza-

tion was identified as any repeat revascularization of the target lesion or target vessel associated with either: 1) ischemic symptoms and/or an abnormal functional study and a  $\geq 50\%$  coronary stenosis by quantitative angiography; or 2) any revascularization of a  $\geq 70\%$  diameter stenosis. All primary and secondary clinical end points were adjudicated by an independent clinical events committee blinded to the patient's treatment assignment.

Secondary angiographic and IVUS efficacy end points included in-stent late lumen loss at 8 months, angiographic binary restenosis (both in-stent and in-segment) at 8 months, and percent volume obstruction assessed by IVUS at 8 months. Development of acquired incomplete late stent apposition at IVUS follow-up was identified according to previously described methods (28). Angiographic binary restenosis was defined as a stenosis  $\geq 50\%$  of the lumen diameter of the target lesion (determined by the core angiographic laboratory). Percent diameter stenosis was defined as  $(1 - [\text{MLD}/\text{reference vessel diameter}]) \times 100$ , and acute gain was defined as the MLD immediately after the procedure minus the MLD before the procedure. Restenosis patterns were characterized according to established criteria (29).

**Statistical methods.** This randomized study was designed to determine the equivalence (non-inferiority) of 8-month in-segment late lumen loss with an equivalence definition (delta) such that the ZES would have a mean in-segment late lumen loss  $\leq 0.2$  mm plus the control SES in-segment late lumen loss. With a 3:1 (ZES/SES) randomization and assuming a common SD of 0.55 mm, a sample size of 436 patients (323 ZES, 113 SES) with at least 80% angiographic follow-up was required for the trial to have 90% statistical power to detect a significant difference at an alpha level of 0.05. Patients were analyzed for all primary and secondary efficacy and safety end points on the basis of the intent-to-treat principle. Baseline characteristics of study patients were summarized in terms of frequencies and percentages for categorical variables and by means with SDs for continuous variables. Categorical variables were compared by Fisher exact test. Continuous variables were compared by the 2-sample *t* test. Cumulative event-free survival was summarized as Kaplan-Meier estimates. A *p* value of 0.05 was established as the level of statistical significance for all tests. All analyses were performed with SAS software (version 8.2 or higher, SAS Institute, Cary, North Carolina).

## RESULTS

**Patient characteristics.** Among 436 patients undergoing elective percutaneous coronary revascularization, 323 patients were randomized to treatment with ZES and 113 patients were treated with SES. No significant differences were present in the baseline clinical or demographic characteristics between patients randomized to receive ZES versus the control SES, except that fewer patients assigned

**Table 1.** Baseline Patient Clinical and Angiographic Characteristics

	Zotarolimus-Stent Group (n = 323)	Sirolimus-Stent Group (n = 113)	p Value
<b>Clinical characteristics</b>			
Age (yrs)	61.42 ± 10.58 (323)	61.73 ± 11.59 (113)	0.80
Male gender (%)	65.3 (211/323)	81.4 (92/113)	0.001
Diabetes mellitus (%)	29.7 (96/323)	28.3 (32/113)	0.81
Hypertension (%)	70.7 (227/321)	74.3 (84/113)	0.54
History of smoking (%)	66.5 (212/319)	75.2 (85/113)	0.10
Hyperlipidemia (%)	83.5 (268/321)	86.7 (98/113)	0.46
Prior myocardial infarction (%)	19.9 (64/321)	20.7 (23/111)	0.89
Angina class III/IV (%)	59.3 (156/263)	55.9 (52/93)	0.62
Prior percutaneous revascularization (%)	22.6 (73/323)	16.8 (19/113)	0.23
Prior coronary bypass surgery (%)	5.3 (17/323)	8.0 (9/113)	0.35
<b>Angiographic characteristics</b>			
Target vessel (%)			0.55
Left anterior descending artery	41.3 (133/322)	39.8 (45/113)	
Left circumflex artery	23.3 (75/322)	28.3 (32/113)	
Right coronary artery	35.4 (114/322)	31.9 (36/113)	
Type B2/C lesions (%)	67.4 (217/322)	56.6 (64/113)	0.05
Reference vessel diameter (mm)	2.75 ± 0.46 (322)	2.79 ± 0.46 (113)	0.49
Lesion length (mm)	14.98 ± 6.20 (321)	14.95 ± 7.28 (112)	0.96
Number of diseased vessels (%)			0.40
1	62.2 (201/323)	58.4 (66/113)	
2	29.1 (94/323)	30.1 (34/113)	
3	8.7 (28/323)	11.5 (13/113)	
Left ventricular ejection fraction (%)	55.66 ± 9.11 (307)	56.28 ± 9.28 (110)	0.54

Values expressed as number (%) or mean (± SD). Angina severity according to Canadian Cardiovascular Society classification.

to ZES were male (65.3% vs. 81.4%,  $p = 0.001$ ) (Table 1). Overall, the mean age was 61.5 years, 21.1% underwent prior percutaneous coronary intervention, 68.8% had a history of smoking, and 29.4% had diabetes mellitus. Most patients (61.2%) had single-vessel coronary disease, and 20.1% of patients had a history of prior myocardial infarction.

Baseline angiographic characteristics were also similar (Table 1), except for a higher frequency of moderate complexity lesions characterized as type B2 or C according to the modified ACC/AHA classification (24) in the ZES group (67.4% vs. 56.6%,  $p = 0.047$ ). Overall, the mean lesion length was 14.97 mm, the average reference vessel diameter was 2.76 mm, and most lesions (40.9%) were located in the left anterior descending artery.

**Procedural and in-hospital outcomes.** The number, length, and diameter of stents implanted were similar in patients assigned to each treatment group (Table 2). The average number of stents/target lesion was 1.15, with overlapping stents in 23.6% of patients. Importantly, device success was significantly higher among patients treated with ZES (98.8% vs. 94.7%,  $p = 0.02$ ). By intention to treat analysis, the reason for device failure in SES cases was an inability to deliver the assigned study stent to the target lesion, except for 1 instance of an inadvertent protocol exclusion, in which a patient was treated with a non-study stent.

In-hospital major adverse events were higher among patients randomized to SES, principally owing to a significantly higher incidence of non-Q-wave myocardial infarction

(0.6% with ZES vs. 3.5% with SES for both non-Q-wave myocardial infarction and in-hospital MACE;  $p = 0.04$ ) (Table 2). Among patients with myocardial infarction, a CK-MB elevation >3 times the upper normal limit occurred in all patients except 1 ZES patient, and a CK elevation >3 times the upper normal limit occurred in only 1 patient, who was treated with SES. Administration of intravenous glycoprotein IIb/IIIa inhibitors did not differ between groups (44.0% with ZES vs. 44.6% with SES,  $p = 0.91$ ). Among patients with myocardial infarction, 2 of the 4 events in the SES group and none in the ZES group were related to sidebranch occlusion. There were no differences in the frequency of myocardial infarction between patients receiving multiple and/or overlapping stents in either treatment group. Procedure success was significantly higher with ZES than with SES (98.1% vs. 91.2%,  $p = 0.002$ ).

**Angiographic and IVUS outcomes.** Eight-month follow-up angiography was performed in 282 (87.3%) of patients in the ZES group and 94 (83.2%) patients in the SES group. There were no differences in baseline characteristics and clinical outcomes in patients who did and those who did not undergo follow-up angiography. Both in-stent late lumen loss and in-stent binary restenosis were significantly higher after ZES versus SES therapy (Table 3). The primary end point, in-segment late lumen loss, was also significantly higher among patients treated with ZES versus SES ( $0.34 \pm 0.44$  mm vs.  $0.13 \pm 0.32$  mm,  $p < 0.001$ ;  $p = 0.65$  for non-inferiority), corresponding to a higher frequency of in-segment binary restenosis (11.7% vs. 4.3%,  $p = 0.04$ ) (Table 3). Although the pattern of in-stent

**Table 2.** Procedural Angiographic Results and In-Hospital Clinical Events

	<b>Zotarolimus-Stent Group (n = 323)</b>	<b>Sirolimus-Stent Group (n = 113)</b>	<b>p Value</b>
Procedural characteristics			
Number of stents	1.14 ± 0.41 (317)	1.19 ± 0.46 (111)	0.28
Stent length (mm)	22.33 ± 6.18 (322)	23.02 ± 7.69 (112)	0.40
Stent diameter (mm)	3.07 ± 0.39 (316)	3.11 ± 0.35 (107)	0.31
Inflation pressure (atm)	13.54 ± 2.51 (318)	14.52 ± 2.89 (110)	<0.01
>1 stent implanted (%)	12.0 (38/317)	16.2 (18/111)	0.26
Minimal luminal diameter (mm)			
Before procedure			
In-lesion	0.92 ± 0.41 (322)	0.90 ± 0.39 (113)	0.60
After procedure			
In-stent	2.67 ± 0.42 (322)	2.67 ± 0.40 (112)	1.00
In-segment	2.26 ± 0.45 (322)	2.28 ± 0.47 (113)	0.82
Diameter stenosis (%)			
Before procedure			
In-lesion	66.79 ± 12.41 (322)	67.91 ± 12.42 (113)	0.41
After procedure			
In-stent	4.35 ± 9.77 (322)	5.92 ± 9.07 (112)	0.14
In-segment	19.43 ± 9.23 (322)	20.17 ± 11.74 (113)	0.55
Device success (%)	98.8 (318/322)	94.7 (107/113)	0.02
Procedural success (%)	98.1 (316/322)	91.2 (103/113)	0.002
In-hospital outcomes			
Death (%)	0 (0/323)	0 (0/113)	—
Myocardial infarction (%)	0.6 (2/323)	3.5 (4/113)	0.04
Q-wave (%)	0 (0/323)	0 (0/113)	—
Non-Q-wave (%)	0.6 (2/323)	3.5 (4/113)	0.04
Stent thrombosis (%)	0 (0/323)	0 (0/113)	—
Target lesion revascularization (%)	0 (0/323)	0 (0/113)	—
Target vessel revascularization (%)	0 (0/323)	0 (0/113)	—
Major adverse cardiac events (%)	0.6 (2/323)	3.5 (4/113)	0.04

Values expressed as number (%) or mean (± SD).

restenosis was most frequently focal in both ZES- and SES-treated patients, the restenosis lesion length was significantly greater in patients treated with ZES (12.94 mm

with ZES vs. 6.46 mm with SES,  $p < 0.001$ ). There were no differences in restenosis within the proximal or distal margins of the stents comparing ZES versus SES patients.

**Table 3.** Angiographic and IVUS Outcomes at Eight Months

	<b>Zotarolimus-Stent Group (n = 323)</b>	<b>Sirolimus-Stent Group (n = 113)</b>	<b>p Value</b>
Quantitative angiography			
Late lumen loss (mm)			
In-stent	0.60 ± 0.48 (281)	0.15 ± 0.34 (94)	<0.001
In-segment	0.34 ± 0.44 (281)	0.13 ± 0.32 (94)	<0.001
Minimal luminal diameter (mm)			
In-stent	2.08 ± 0.57 (282)	2.52 ± 0.56 (94)	<0.001
In-segment	1.92 ± 0.52 (282)	2.16 ± 0.50 (94)	<0.001
Diameter stenosis (%)			
In-stent	24.31 ± 17.08 (282)	10.98 ± 15.88 (94)	<0.001
In-segment	29.88 ± 15.27 (282)	23.86 ± 13.87 (94)	<0.001
Binary restenosis (%)			
In-stent	9.2 (26/282)	2.1 (2/94)	0.02
In-segment	11.7 (33/282)	4.3 (4/94)	0.04
Proximal margin	1.5 (4/270)	1.1 (1/87)	1.0
Distal margin	1.4 (4/281)	1.1 (1/92)	1.0
IVUS outcomes			
Volume obstruction (%)	16.1 ± 10.8 (185)	2.7 ± 3.1 (61)	<0.001
Incomplete stent apposition (%)			
Baseline	12.6 (31/247)	17.9 (17/95)	0.22
Persistent	6.8 (13/190)	11.8 (8/68)	0.21
Resolved	5.8 (11/190)	7.4 (5/68)	0.77
Acquired	0.5 (1/190)	5.9 (4/68)	0.02

IVUS = intravascular ultrasound.



**Table 4.** Clinical Events at Nine Months

	Zotarolimus-Stent Group (n = 323)	Sirolimus-Stent Group (n = 113)	p Value	Relative Risk [95% Confidence Interval]
Death (%)	0.6 (2/316)	0 (0/113)	1.0	—
Myocardial infarction (%)	0.6 (2/316)	3.5 (4/113)	0.04	0.18 [0.03, 0.96]
Q-wave (%)	0 (0/316)	0 (0/113)	—	—
Non-Q-wave (%)	0.6 (2/316)	3.5 (4/113)	0.04	0.18 [0.03, 0.96]
Stent thrombosis (%)	0 (0/316)	0 (0/113)	—	—
Target lesion revascularization (%)	6.3 (20/316)	3.5 (4/113)	0.34	1.79 [0.62, 5.12]
Percutaneous	5.4 (17/316)	3.5 (4/113)	0.61	1.52 [0.52, 4.42]
Surgical	0.9 (3/316)	0 (0/113)	0.57	—
Target vessel revascularization—not involving target lesion (%)	6.0 (19/316)	5.3 (6/113)	1.0	1.13 [0.46, 2.76]
Percutaneous	5.7 (18/316)	5.3 (6/113)	1.0	1.07 [0.44, 2.63]
Surgical	0.3 (1/316)	0 (0/113)	1.0	—
Major adverse cardiac events (%)	7.6 (24/316)	7.1 (8/113)	1.0	1.07 [0.50, 2.32]
Target vessel failure (%)	12.0 (38/316)	11.5 (13/113)	1.0	1.05 [0.58, 1.89]

Immediate post-procedural IVUS measurements did not differ significantly among the 2 study groups. Follow-up IVUS at 8 months (with images suitable for analysis) was performed in 187 (59.2%) patients in the ZES group and 61 (54.0%) patients in the SES group. At 8 months, percent volume obstruction ( $16.1 \pm 11\%$  vs.  $2.7 \pm 3\%$ ,  $p < 0.001$ ) was significantly greater with ZES compared with SES (Table 3). Importantly, newly observed incomplete late stent apposition with abnormal remodeling and vessel expansion occurred in 4 patients (5.9%) treated with SES and in only 1 (0.5%) patient receiving ZES ( $p = 0.02$ ) (Table 3).

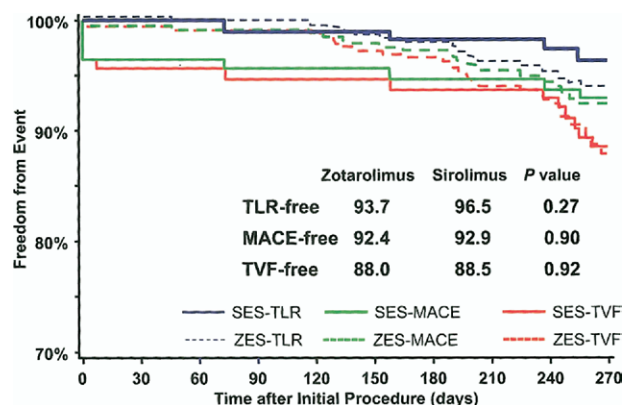
**Nine-month clinical outcomes.** Clinical follow-up was completed in 316 patients (97.8%) in the ZES group and in 113 patients (100%) in the SES group (Table 4). There were no episodes of acute, subacute, or late stent thrombosis in either treatment group. There were 2 (0.6%) deaths in the ZES group and none in the SES group. The deaths in the ZES group were due to stroke in 1 patient and pancreatic cancer in the other patient. There were no out-of-hospital myocardial infarctions in either group, such that the early lower frequency of myocardial infarctions with ZES persisted during the follow-up period. The occurrence of clinically driven target lesion revascularization did not significantly vary between the ZES and SES groups (6.3% ZES vs. 3.5% SES,  $p = 0.34$ ) (Table 4). Target vessel revascularization unrelated to the target lesion was also similar between ZES and SES groups (6.0% with ZES vs. 5.3% with SES,  $p = 1.0$ ). Target lesion revascularization adjudicated as non-clinically driven (i.e., occurring without an abnormal functional study or  $\geq 70\%$  stenosis) occurred in an additional 11 (3.5%) patients treated with ZES; therefore, the total (clinically and non-clinically driven) target lesion revascularization rates were 9.8% and 3.5% for the ZES and SES groups, respectively ( $p = 0.04$ ). There were no significant differences between ZES and SES in the occurrence of MACEs (7.6% vs. 7.1%,  $p = 1.0$ ) and target vessel failure (12.0% vs. 11.5%,  $p = 1.0$ ). Actuarial event-free survival at 9 months for clinically driven target lesion

revascularization, MACEs, and target vessel failure did not significantly differ among ZES and SES patients (Fig. 1).

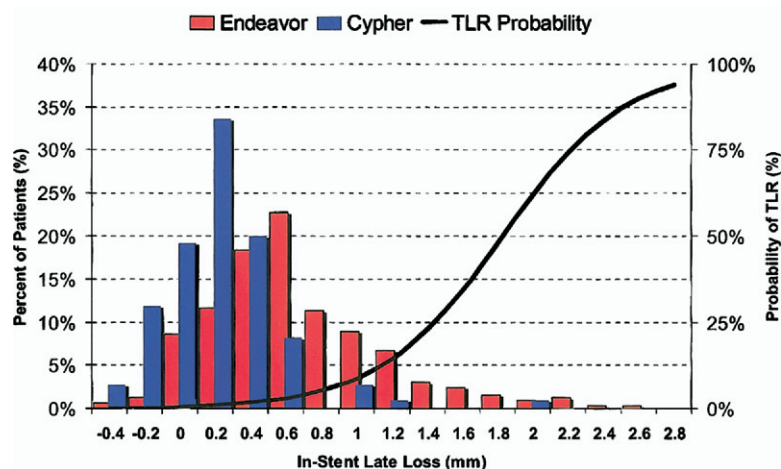
## DISCUSSION

In this prospective, randomized trial comparing the clinical efficacy, safety, and angiographic outcomes among patients treated with ZES and SES, treatment with ZES was associated with increased neointimal hyperplasia resulting in greater angiographic late lumen loss.

The reasons for higher late lumen loss observed with ZES in this trial compared with SES (the primary end point) and other studies are incompletely understood. Among patients treated with ZES in the first-in-man ENDEAVOR I (100-patient) and large (1,200-patient), randomized ENDEAVOR II trials (8,30), for example, angiographic measurement of in-stent late lumen loss was 0.61 mm in both studies, compared with 0.60 mm in the current study. Increased neointimal hyperplasia with ZES might be due to differences in biological activity of zotarolimus compared with sirolimus, although in vitro cell culture experiments and animal studies would suggest equivalent nanomolar potencies in suppressing smooth muscle cell proliferation (23).



**Figure 1.** Kaplan-Meier event-free survival to 9 months for patients treated with zotarolimus- (ZES) and sirolimus-eluting (SES) stents. MACE = major adverse cardiac events; TLR = target lesion revascularization; TVF = target vessel failure.



**Figure 2.** Logistic regression relationship between late lumen loss and target lesion revascularization (TLR) for patients treated with zotarolimus-eluting stents.

Another potential reason for the observed differences is that the more rapid elution kinetics of zotarolimus from the phosphorylcholine polymer—95% eluted in approximately 2 weeks (23)—compared with the slower release of sirolimus from the polyethylene-co-vinyl acetate/poly n-butyl methacrylate co-polymer—95% eluted in approximately 6 weeks—might significantly influence biological efficacy. Optimal suppression of procedural-induced injury responses resulting in inflammation and subsequent intimal hyperplasia might require more prolonged tissue exposure to the therapeutic agent. Lastly, there might be differences in biological responses to either the stent or the phosphorylcholine polymer itself.

Regarding secondary end points, the results from this trial are the first among comparative drug-eluting stent trials to demonstrate a statistically significant difference in both procedural device success and in-hospital clinical outcome. First, device success was significantly higher with ZES, owing to enhanced stent deliverability likely associated with a more flexible, low profile thin-strut cobalt alloy stent. Second, although infrequent in both groups, the occurrence of in-hospital non-Q-wave myocardial infarctions was significantly lower with ZES compared with SES. This observation is more difficult to reconcile, given that most procedural, demographic, and baseline angiographic characteristics did not differ between the 2 groups.

Although the angiographic and IVUS follow-up analyses favored SES compared with ZES, differences in clinical outcome were less consistent. Most clinical end points did not statistically differ between these 2 drug-eluting stents (Table 4), including clinically driven target lesion revascularization (6.3% for ZES vs. 3.5% for SES,  $p = 0.34$ ). However, overall target lesion revascularization (clinically and non-clinically driven) was significantly more common in the ZES group. The modest but statistically significant benefit associated with lower peri-procedural myocardial infarction rates with ZES was offset by the slightly higher follow-up target lesion revascularization frequencies, such

that the composite target vessel failure and MACE values for ZES and SES were similar. As with previous studies using paclitaxel-eluting stents (3,6,7), a discordance might exist between angiographic and clinical outcomes in this ZES trial, suggesting that there might be an angiographic late lumen loss threshold or “window” below which the occurrence of repeat clinically driven revascularization events is unlikely (Fig. 2). In low- or medium-complexity lesions, an in-stent late loss of 0.60 mm and an in-segment late loss of 0.34 mm were in most instances well tolerated and not sufficient to induce important changes in clinically driven target lesion revascularization compared with SES. Of course, in higher complexity lesions (such as diffuse disease, in-stent restenosis, or small vessels), where there is the potential for an upward drift in late lumen loss, greater differences between ZES and SES might become apparent. At present, an international “open” registry with ZES is ongoing to provide insights regarding the clinical efficacy of ZES in a broad, unselected patient population with greater lesion complexity and in varied clinical settings.

**Study limitations.** There are several limitations of this study. Because the primary objective of the study was to compare an angiographic surrogate end point—follow-up in-segment late lumen loss—between 2 drug-eluting stents, the sample size did not enable adequate statistical power to rigorously examine differences among pertinent clinical end points. Moreover, the unbalanced randomization resulted in a very small SES comparison group, such that results for SES were subject to potential over-interpretation due to broad confidence intervals. It is also noteworthy that the differences between ZES and SES were somewhat exaggerated in this clinical trial, owing to an unexpectedly low SES in-segment late lumen loss compared with other recent SES clinical trials (1,2,17). Unlike previous double-blinded drug-eluting stent versus bare metal stent clinical trials, this study was single-blinded, and the identity of the treatment stent was known to the interventional operator, which could introduce bias in procedural outcomes and the performance

of repeat revascularization. As stated, the results from this trial are specific to the patient population studied and cannot be generalized to the much broader population of patients with more complex lesion morphologies.

**Conclusions.** As demonstrated in this ZES versus SES clinical trial, ZES was shown to have significantly higher angiographic late lumen loss. Although most other angiographic outcomes favored SES, differences in secondary clinical end points were not consistent between the 2 stent groups. Clinical interventional operators will have to consider the overall attributes of ZES versus SES in making decisions concerning preferential device use under specific clinical circumstances.

**Reprint requests and correspondence:** Dr. David E. Kandzari, Room 7063, Duke Clinical Research Institute, 2400 Pratt Street, Durham, North Carolina 27705. E-mail: david.kandzari@duke.edu.

## REFERENCES

- Morice MC, Serruys PW, Sousa JE, et al. A randomized comparison of a sirolimus-eluting stent with a standard stent for coronary revascularization. *N Engl J Med* 2002;346:1773-80.
- Moses JW, Leon MB, Popma JJ, et al., for the SIRIUS Investigators. Sirolimus-eluting stents versus standard stents in patients with stenosis in a native coronary artery. *N Engl J Med* 2003;349:1315-23.
- Stone GW, Ellis SG, Cox DA, et al. A polymer-based, paclitaxel-eluting stent in patients with coronary artery disease. *N Engl J Med* 2004;350:221-31.
- Schampaert E, Cohen EA, Schluter M, et al., for the C-SIRIUS Investigators. The Canadian study of the sirolimus-eluting stent in the treatment of patients with long de novo lesions in small native coronary arteries (C-SIRIUS). *J Am Coll Cardiol* 2004;43:1110-5.
- Schofer J, Schluter M, Gershlick AH, et al., for the E-SIRIUS Investigators. Sirolimus-eluting stents for treatment of patients with long atherosclerotic lesions in small coronary arteries: double-blind, randomised controlled trial (E-SIRIUS). *Lancet* 2003;362:1093-9.
- Stone GW, Ellis SG, Cannon L, et al., for the TAXUS V Investigators. Comparison of a polymer-based paclitaxel-eluting stent with a bare metal stent in patients with complex coronary artery disease: a randomized controlled trial. *JAMA* 2005;294:1215-23.
- Dawkins KD, Grube E, Guagliumi G, et al. Clinical efficacy of polymer-based paclitaxel-eluting stents in the treatment of complex, long coronary artery lesions from a multicenter, randomized trial. Support for the use of drug-eluting stents in contemporary clinical practice. *Circulation* 2005;112:3306-13.
- Fajadet J, Wijns W, Laarman GJ, et al. Randomized, double-blind, multicenter study of the Endeavor zotarolimus-eluting phosphorylcholine-encapsulated stent for treatment of native coronary artery lesions: clinical and angiographic results of the ENDEAVOR II trial. *Circulation* 2006;114:798-806.
- Lemos PA, Serruys PW, van Domburg RT, et al. Unrestricted utilization of sirolimus-eluting stents compared with conventional bare stent implantation in the "real world": the rapamycin-eluting stent evaluated at Rotterdam Cardiology Hospital (RESEARCH) registry. *Circulation* 2004;109:190-5.
- Ong ATL, Serruys PW, Aoki J, et al. The unrestricted use of paclitaxel-versus sirolimus-eluting stents for coronary artery disease in an unselected population: one-year results of the Taxus-Stent Evaluated at Rotterdam Cardiology Hospital (T-SEARCH) registry. *J Am Coll Cardiol* 2005;45:1135-41.
- Lemos PA, Hoye A, Goedhart D, et al. Clinical, angiographic, and procedural predictors of angiographic restenosis after sirolimus-eluting stent implantation in complex patients. *Circulation* 2004;109:1366-70.
- Windecker S, Remondino A, Eberli FR, et al. Sirolimus-eluting and paclitaxel-eluting stents for coronary revascularization. *N Engl J Med* 2005;353:653-62.
- Dibra A, Kastrati A, Mehillia J, et al., ISAR-DIABETES Study Investigators. Paclitaxel-eluting or sirolimus-eluting stents to prevent restenosis in diabetic patients. *N Engl J Med* 2005;353:663-70.
- Goy JJ, Stauffer JC, Siegenthaler M, Benoit A, Seydoux C. A prospective randomized comparison between paclitaxel and sirolimus stents in the real world of interventional cardiology: the TAXI trial. *J Am Coll Cardiol* 2005;45:308-11.
- Kastrati A, Mehilli J, von Beckerath N, et al., ISAR-DESIRE Study Investigators. Sirolimus-eluting stent or paclitaxel-eluting stent vs balloon angioplasty for prevention of recurrences in patients with coronary in-stent restenosis: a randomized controlled trial. *JAMA* 2005;293:165-71.
- Kastrati A, Dibra A, Eberle S, et al. Sirolimus-eluting stents vs paclitaxel-eluting stents in patients with coronary artery disease: meta-analysis of randomized trials. *JAMA* 2005;294:819-25.
- Morice MC, Colombo A, Meier B, et al., for the REALITY trial Investigators. Sirolimus-versus paclitaxel-eluting stents in de novo coronary artery lesions: the REALITY trial: a randomized controlled trial. *JAMA* 2006;295:895-904.
- de Lezo JS, Medina A, Pan M, et al. Drug-eluting stents for complex lesions: latest angiographic data from the randomized rapamycin versus paclitaxel CORPAL study (abstr). *J Am Coll Cardiol* 2005;45 Suppl A:75A.
- Kereiakes DJ, Kuntz RE, Mauri L, Krucoff MW. Surrogates, sub-studies, and real clinical end points in trials of drug-eluting stents. *J Am Coll Cardiol* 2005;45:1206-12.
- Moliterno DJ. Healing Achilles—sirolimus versus paclitaxel. *N Engl J Med* 2005;353:724-6.
- Hayward JA, Chapman D. Biomembrane surfaces as models for polymer design: the potential for haemocompatibility. *Biomaterials* 1984;5:135-42.
- Schwartz RS, Burke SE, Cromack K, et al. Marked neointimal inhibition from a drug eluting stent: effects of local ABT-578 in the porcine coronary model (abstr). *Circulation* 2002;106 Suppl II:II448.
- Carter AJ, Brodeur A, Hasting W, et al. The effects of a diffusion barrier on the elution characteristics of ABT-578 via a phosphorylcholine matrix (abstr). *J Am Coll Cardiol* 2006; 47 Suppl B:3B.
- Ellis SG, Vandormael MG, Cowley MJ, et al. Coronary morphologic and clinical determinants of procedural outcome with angioplasty for multivessel coronary disease: implications for patient selection. *Circulation* 1990;82:1193-202.
- van der Zwet PM, Reiber JH. A new approach for the quantification of complex lesion morphology: the gradient field transform: basic principles and validation results. *J Am Coll Cardiol* 1994;24:216-24.
- Sonoda S, Morino Y, Ako J, et al., for the SIRIUS Investigators. Impact of final stent dimensions on long-term results after sirolimus-eluting stent implantation: serial intravascular ultrasound analysis from the SIRIUS trial. *J Am Coll Cardiol* 2004;43:1959-63.
- Mintz GS, Nissen SE, Anderson WD, et al. American College of Cardiology clinical expert consensus document on standards for acquisition, measurement and reporting of intravascular ultrasound studies (IVUS). A report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents. *J Am Coll Cardiol* 2001;37:1478-92.
- Ako J, Morino Y, Honda Y, et al. Late incomplete stent apposition after sirolimus eluting stent implantation: a serial intravascular ultrasound analysis. *J Am Coll Cardiol* 2005;46:1002-5.
- Mehran R, Dangas G, Abizaid AS, et al. Angiographic patterns of in-stent restenosis: classification and implications for long-term outcome. *Circulation* 1999;100:1872-8.
- Meredith IT, Ormiston J, Whitbourn R, et al. First-in-human study of the Endeavor ABT-578-eluting phosphorylcholine-encapsulated stent system in de novo native coronary artery lesions: Endeavor I Trial. *EuroInterv* 2005;2:157-64.

## APPENDIX

For a list of the ENDEAVOR III trial study sites and principal investigators, please see the online version of this article.

# Exhibit 3



[PRINT](#)

## Two-year results from ENDEAVOR III point to safety, efficacy

April 4, 2007 | Shelley Wood



**New Orleans, LA** - Two-year follow-up from the **ENDEAVOR III** trial suggests that the Endeavor zotarolimus-eluting stent may be equivalent to the sirolimus-eluting Cypher stent, in terms of clinical end points. Rates of major adverse cardiac events (MACE) and target lesion revascularizations (TLR) at two years were not statistically different for the two drug-eluting stents (DES), although fewer patients randomized to the Endeavor experienced periprocedural non-Q-wave MI, a difference that was maintained over the two years of follow-up.

**Dr Martin Leon** (Columbia University, New York) presented the two-year results during the **American College of Cardiology 2007 Scientific Sessions** last week.

The two-year results are relatively good news for a stent program that appeared poised for a rocky ride when the trial results were first unveiled at the prespecified eight-month follow-up. As reported by **heartwire**, the Endeavor failed to achieve its primary end point of noninferiority for in-segment late lumen loss at eight months when compared with the Cypher, although clinical and angiographic outcomes were more or less equivalent. At the time, these results were reported by co-primary investigator for the trial, **Dr David Kandzari**, who has since left academia for Cordis/Johnson & Johnson.

The ENDEAVOR III late results come during a sea change in the DES arena, where the focus has shifted from a fixation on late loss to concerns over stent thrombosis and associated deaths and MI. In the early days of DES trials, minimal or no late loss was held up as the new gold standard. As a result, the eight-month in-stent late loss in ENDEAVOR III for the Endeavor stent, at 0.62 mm as compared with the Cypher at 0.15 mm ( $p < 0.001$ ), and in-segment, at 0.36 mm vs 0.13 mm ( $p < 0.001$ ), led to gloomy speculation about the Endeavor stent's future.

"The original study was meant to have a primary surrogate angiographic end point, and it failed to meet that end point," Leon told **heartwire**. "But the trial, of course, was planned many, many years ago, before anybody knew that the late loss would be as high as it was with the Endeavor stent, but at the same time before anybody knew that with a late loss of 0.6 mm you could still have TLR in the mid-single-digit numbers. I think we're still learning about the relationship between TLR and in-stent late loss."

### Small sample size

The only statistically significant difference between the two groups at 24 months was in MI rates, all periprocedural non-Q-wave MIs, at 0.6% in the Endeavor-treated patients and 3.6% in Cypher-treated patients ( $p = 0.04$ ), a difference that might have been explained by the manner in which events were measured in the trial.

"We don't know exactly why, in this study, the non-Q-wave MI rates were so low," Leon said. "It could be there was less side-branch occlusion, which is something people have hypothesized based on the geometry of the stent design itself. Also, the polymer is very thin—less than 5  $\mu\text{m}$  in total thickness, which means it's almost a quarter of the thickness of the Taxus polymer and less than half the thickness of the Cypher polymer. And it may be that the polymer in and of itself caused less in the way of platelet adhesion, side-branch occlusion, we don't know for sure. You can also argue that this was a relatively small study and sometimes you see statistical significance that may be not biologically meaningful, but just due to the large confidence intervals of a small sample size."

Small sample size could also be scrutinized for other end points. While differences in TLR rates between the two stents were not statistically significant, numerically TLRs were greater in the Endeavor stent-treated patients, while deaths were numerically lower.

### ENDEAVOR III: Clinical events at two years

Event	Endeavor, n=313 (%)	Cypher, n=112 (%)	p
All death	1.6	4.5	0.14
Q-wave MI	0	0	—
Non-Q-wave MI	0.6	3.6	0.04
Stent thrombosis	0	0	—
TLR	7.0	4.5	0.50
MACE	9.3	11.6	0.47

To download table as a slide, click on slide logo below

Leon told **heartwire** that the two-year results from ENDEAVOR III alone do not add much to the stent-thrombosis debate, since rates of stent thrombosis per the trial's definition were zero between both stents. However, in an analysis of all the Endeavor stent data out to two years—more than 1300 patients—there have been no reported stent thromboses, he said.

"Now we're beginning to achieve a large-enough sample size where our confidence about late stent thrombosis is increasing," he said. "It's by no means definitive: I'm anxious to see three-year follow-up from **ENDEAVOR II** and whether these results continue to sustain themselves. But if we don't see significant late stent thrombosis at three years, then I think people will feel more confident that among the DES currently available—the Cypher or Taxus—this appears to have a better safety profile."

### The end of surrogate outcomes

At the very least, the two-year ENDEAVOR III results add muscle to the push to exclude surrogate outcomes from primary end points in DES trials.

"I think a lot of people—me included—were a little bit naive," Leon said. "When we heard the **RAVEL** results, with no late loss and zero restenosis, everyone was ecstatic. But I think we learned since then that probably that degree of late loss reduction does impair healing sufficiently, and it may induce some negative biologic consequences. So I think that people are willing to concede that a somewhat higher late loss is acceptable."

Whether accepting some late loss truly leads to improved safety without sacrificing meaningful reductions in TLR remains to be seen. Three-year results for ENDEAVOR II will be reported at the **EuroPCR** meeting in May, he noted. Nine-month clinical and eight-month angiographic results from **ENDEAVOR IV**, with the Taxus stent as the comparator in 1500 patients, are to be presented at **TCT 2007**.



### Related links

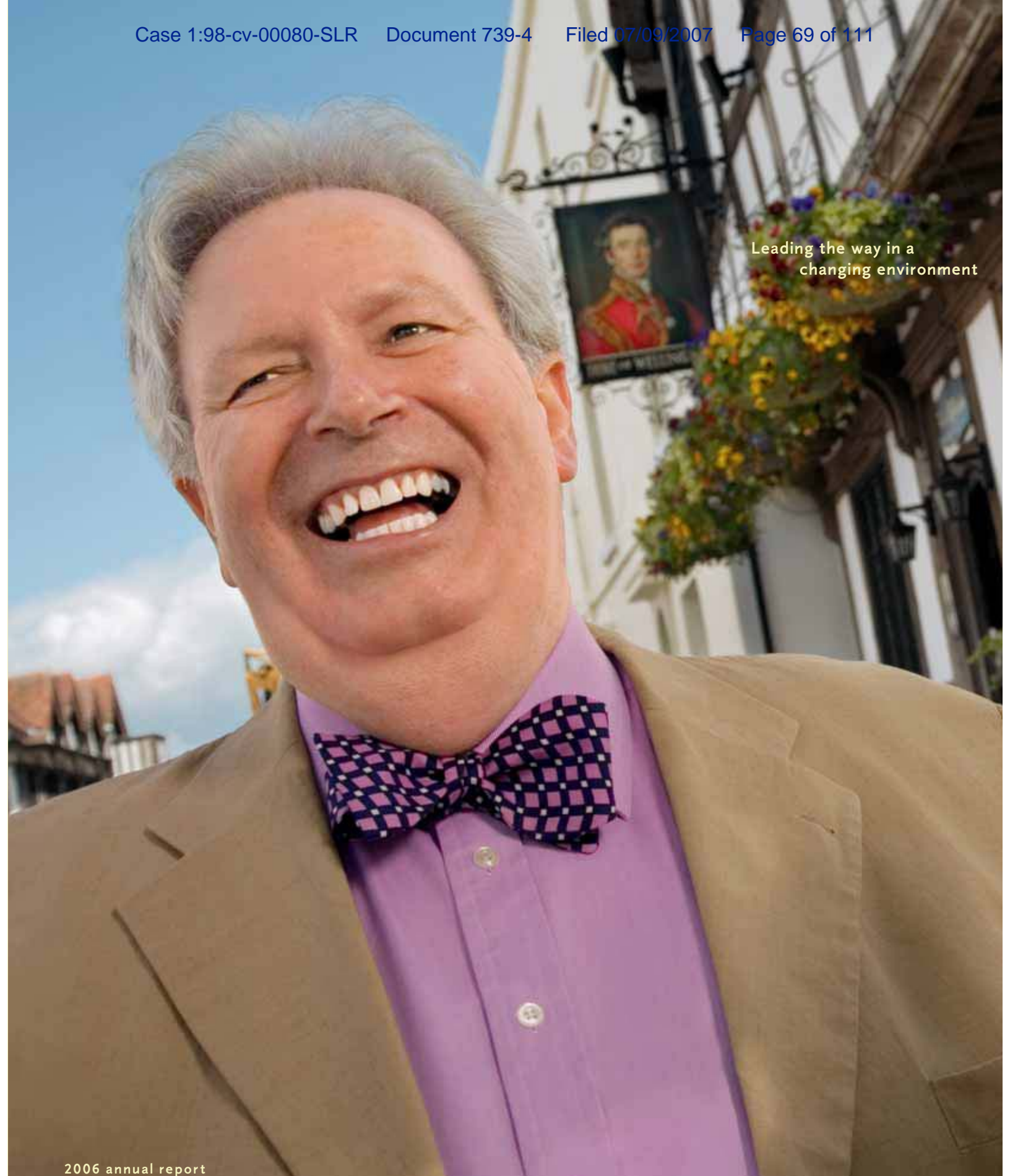
- Late lumen loss a problem once again for the new Endeavor stent  
[*HeartWire* > *Interventional cardiology*; Oct 17, 2005]
- Late loss in ENDEAVOR II dampens enthusiasm, despite improved clinical, angiographic outcomes over bare stent  
[*HeartWire* > *Interventional cardiology*; Mar 07, 2005]
- Fears of catch-up phenomenon mar otherwise positive 12-month results for ENDEAVOR I  
[*HeartWire* > *Other News*; May 25, 2004]

Two-year results from ENDEAVOR in point to safety, efficacy

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# EXHIBIT 17



Leading the way in a  
changing environment

2006 annual report



**Medtronic**  
*Alleviating Pain • Restoring Health • Extending Life*



## Management's Discussion and Analysis

### of Financial Condition and Results of Operations *(continued)*

through the urethra to destroy a precisely targeted area of an enlarged prostate. FDA approval of PROSTIVA RF was received in May 2006.

- Acceptance of our next generation InterStim (InterStim II) which is expected to be launched in the U.S. in the first half of fiscal year 2007 pending FDA approval. The InterStim II device is expected to meet the needs of patients who seek a smaller generator for the treatment of urinary control. Conformité Européenne approval, or CE Mark approval of InterStim II was received in April 2006.

**Vascular** Vascular products consist of coronary, endovascular, and peripheral stents and related delivery systems, stent graft systems, distal embolic protection systems and a broad line of balloon angioplasty catheters, guide catheters, guidewires, diagnostic catheters and accessories. Vascular net sales for fiscal year 2006 increased 10 percent from the prior fiscal year to \$939.4 million. Foreign currency translation had an unfavorable impact on net sales of \$23.7 million when compared to the prior fiscal year. Coronary Vascular net sales increased 12 percent in comparison to the prior fiscal year. The growth in Coronary Vascular net sales was primarily a result of the second quarter fiscal year 2006 release of our Endeavor DES in approximately 85 markets outside the U.S., and the worldwide strong performance in our other coronary products, including balloons and guidewires. Endeavor DES sales grew to \$138.0 million during fiscal year 2006, while stent sales in the U.S. were only \$24.0 million of the total worldwide stent sales of \$365.5 million. Endovascular net sales increased 9 percent in comparison to the prior fiscal year. Endovascular results were primarily a result of solid performance of the Talent Stent Graft System outside the U.S., which is used to treat abdominal aortic aneurysms (AAA), and the recently released Valiant Thoracic Stent Graft outside the U.S. The Valiant stent graft is a next-generation stent graft used for the minimally invasive repair of the thoracic aorta, the body's largest artery, for several disease states including aneurysms, penetrating ulcers, acute or chronic dissections, and contained or traumatic ruptures. The Valiant stent graft was approved in Europe in March 2005.

Vascular net sales for fiscal year 2005 increased 1 percent from fiscal year 2004 to \$851.3 million. Foreign currency translation had a favorable impact on net sales of \$26.5 million when compared to fiscal year 2004. Coronary Vascular net sales were flat in comparison to fiscal year 2004 as a result of declining U.S. coronary stent sales offset by the positive effects of a weaker U.S. dollar in comparison to fiscal year 2004 and continued strong acceptance of the Driver

Coronary Stent in markets outside the U.S., where drug-eluting stent use had not yet dominated the market. The Driver is our cobalt-alloy coronary stent, introduced in fiscal year 2004. The cobalt-alloy allows for engineering of thinner struts and provides greater maneuverability in placing the stent. Also contributing to the fiscal year 2005 results was a net sales increase of 5 percent in Endovascular. Endovascular increases were primarily a result of strong growth in sales of the Talent Stent Graft System outside the U.S. Peripheral Vascular fiscal year 2005 net sales were flat in comparison to fiscal year 2004.

Looking ahead, we expect our Vascular operating segment should benefit from the following:

- We anticipate continued growth in fiscal year 2007 from our launches of Endeavor DES in France, China and Australia in calendar year 2006. The Endeavor stent was the first cobalt-alloy platform in the DES market, and we believe it offers physicians excellent deliverability and a strong safety profile.
- Our anticipated entry into the U.S. DES market. The clinical trials for our Endeavor DES began in fiscal year 2003 and clinical results presented at the European Society of Cardiology, the Transcatheter Cardiovascular Therapeutics and the Paris Course on Revascularization conferences further expanded the medical evidence supporting the clinical performance of the Endeavor DES. In addition, we filed our first Pre-market Approval (PMA) module for Endeavor DES with the FDA in early October 2005 and enrollment of the ENDEAVOR IV clinical trial is progressing as planned. As of the end of fiscal year 2006, we had enrolled over 1,300 patients. Assuming continued positive results from these trials and our current schedule, we anticipate U.S. approval of the Endeavor DES in calendar year 2007.
- Continued market penetration of the Talent AAA Stent Graft and Valiant Thoracic Stent Graft in the European markets. The Valiant device contains the Xcelerant Delivery System, which is designed to provide physicians with a smooth, controlled and trackable delivery platform. The Xcelerant system was launched in fiscal year 2005 in markets outside of the U.S., excluding Japan.
- Acceptance of the Exponent RX Self-Expanding Carotid Stent and Interceptor PLUS Carotid Filter System in markets outside of the U.S. Together, these products provide patients afflicted by carotid artery disease with a new, minimally-invasive treatment option to surgical procedures for the prevention of stroke. The stent and filter system received regulatory

# EXHIBIT 18



## News Release

### Medtronic Media Contacts:

[Daniel Beach](#), Public and Media Relations , +44 1923 205 149  
Mobile phone: +44 77 47 536 313

### Medtronic announces ENDEAVOR II 30-day safety data at PCR

**PARIS - May 26, 2004** - Richard Kuntz, M.D., Associate Professor, Harvard Medical School and Chief, Division of Clinical Biometrics, Brigham and Women's Hospital, Boston, and Co-Principal Investigator of the ENDEAVOR II Clinical Trial, presented positive 30-day safety data today at the Paris Course on Revascularization (PCR). The ENDEAVOR II Trial is a randomized, double-blind trial evaluating the safety and efficacy of the Endeavor™ Drug Eluting Coronary Stent compared to Medtronic's Driver™ cobalt alloy stent. Data from the trial will be used to support product approvals globally. ENDEAVOR II includes 1,200 patients enrolled at more than 70 hospitals throughout Europe, the Middle East and Asia Pacific. The primary endpoint of the study is Target Vessel Failure (TVF) at nine months. The other Co-Principal Investigators for ENDEAVOR II are Dr. William Wijns, M.D., Co-Director, Cardiovascular Center, OLV Ziekenhuis, Aalst, Belgium; and Dr. Jean Fajadet, M.D., Clinique Pasteur Unité de Cardiologie Interventionnelle, Toulouse, France.

For ENDEAVOR II, data are presented in a blinded fashion with no indication of which group received the Endeavor or Driver stent. At 30 days, Dr. Kuntz presented hierarchical data that showed a Major Adverse Cardiac Event (MACE) rate of 2.9 percent in Group Y (n=596) and 3.5 percent in Group Z (n=595). Target Lesion Revascularization (TLR) at 30 days was 0.2 percent for Group Y and 0.3 percent for Group Z. Target Vessel Revascularization (TVR) at 30 days was 0.3 percent for Group Y and 0.0 percent for Group Z.

"Both Group Y and Group Z's MACE rates are fully in the expected levels for this type of study," said Dr. Kuntz. "We also know that the device success, or the percent of procedures that the stent was successfully deployed, was 99.3 percent in both Group Y and Group Z. This data, combined with the device success demonstrated in the ENDEAVOR I clinical trial, further illustrates that the Driver stent platform - the stent platform used in the Endeavor drug eluting stent - is highly deliverable."

"As the pivotal trial in our ENDEAVOR Clinical Program, we are pleased to see the early results have confirmed the safety of the device at the customary 30-day analysis point, and we look forward to seeing the next set of clinical data on the trial," said Scott Ward, president of Medtronic Vascular.

### Investor Webcast to Discuss ENDEAVOR Clinical Trial Results

Medtronic will conduct an investor webcast to provide an overview and analysis of the ENDEAVOR I and ENDEAVOR II Clinical Data presented at PCR on Wednesday, May 26, 12:30 EST / 11:30 CST. The briefing will include a review of the ENDEAVOR trial data by a panel of leading physicians and an analysis from Medtronic senior



management. The webcast can be accessed at [www.medtronic.com/corporate/invest.html](http://www.medtronic.com/corporate/invest.html).

### **Components of Medtronic's Endeavor Drug Eluting Coronary Stent Program**

The Medtronic Endeavor Drug Eluting Coronary Stent system combines Medtronic's Driver Coronary Stent, the drug ABT-578 and a PC polymer into a drug eluting stent system designed to reduce restenosis.

ABT-578 is a unique, patent-protected compound licensed to Medtronic by Abbott Laboratories. ABT-578 is designed to inhibit the cellular process that leads to restenosis. Medtronic also licenses Abbott's proprietary phosphorylcholine coating technology (PC Technology™ is owned by Biocompatibles UK Ltd.). PC Technology is designed to serve as the "delivery matrix," which controls the elution, or release, of ABT-578 directly into the arterial wall. Finally, Medtronic's Endeavor stent system utilizes the original Driver Coronary Stent, which is approved in both the United States and Europe. In Europe, the Driver is approved for both large and small vessels. In the U.S., the Driver is approved for large vessels. The Driver Coronary Stent leverages Medtronic's long expertise in utilizing implantable metal alloys, such as cobalt chromium alloys. Using a cobalt chromium alloy permits the Driver stent to have thinner struts, a lower profile and better deliverability in the vessel without compromising radial strength and visibility.

### **The ENDEAVOR Clinical Trial Program**

Medtronic's ENDEAVOR Clinical Trial Program is designed to support the approval of the Endeavor Drug Eluting Coronary Stent in countries throughout the world. In addition to the ENDEAVOR II trial explained above, the program consists of the following additional clinical studies:

#### **ENDEAVOR I**

The ENDEAVOR I Clinical Trial is a 100-patient, prospective, multi-center trial studying the safety of the Endeavor Coronary Drug Eluting Stent for the treatment of de novo coronary lesions in native coronary arteries. The trial began in 2003 and is being conducted at sites in Australia and New Zealand. ENDEAVOR I 12-month data was presented at the Paris Course on Revascularization (PCR) yesterday.

#### **ENDEAVOR II Expanded Trial Registry**

The ENDEAVOR II Expanded Trial Registry began in March 2004 and will include a total of 300 patients at approximately 15 sites outside the United States. The purpose of the trial is to expand patient exposure to the Endeavor stent and collect further data to support product approvals globally as necessary. The trial will include the standard endpoints of MACE rate at 30 days, TLR, TVR and TVF at nine months with angiographic and IVUS follow-up at eight months.

#### **ENDEAVOR III**

The ENDEAVOR III Clinical Trial began in February 2004 and is a randomized trial evaluating the safety and efficacy of the Endeavor Drug Eluting Coronary Stent as compared to the Cypher™ Sirolimus-eluting stent marketed by Cordis Corporation, a Johnson & Johnson company. The study will include 436 patients (327 receiving the Endeavor stent) and has a primary endpoint of in-segment late lumen loss at eight months. Secondary endpoints include TLR, TVR, and TVF rates at nine months and Angiographic Binary Restenosis (ABR) rate at eight months.

Medtronic, Inc., headquartered in Minneapolis, is the world's leading medical technology company, providing lifelong solutions for people with chronic disease. Its Internet address is [www.medtronic.com](http://www.medtronic.com).

Caution: The Endeavor Drug Eluting Coronary Stent is an investigational device. The device is limited by federal (or United States) law to investigational use only. ABT-578 is an investigational drug and is not approved by the FDA.

**Any statements made about the company's anticipated financial results and regulatory approvals are forward-looking statements subject to risks and**

**uncertainties such as those described in Medtronic's Annual Report on Form 10-K for the year ended April 25, 2003. Actual results may differ materially from anticipated results.**

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Medtronic, Inc. 2007

# EXHIBIT 19

**FOLEY & LARDNER LLP**  
ONE MARITIME PLAZA, 6<sup>TH</sup> FLOOR  
SAN FRANCISCO, CA 94111-3409  
TELEPHONE: (415) 434-4484  
FACSIMILE: (415) 434-4507

NANCY J. GEENEN, BAR NO. 135988  
ngeenen@foley.com  
DAVID B. MOYER, BAR NO. 197739  
dmoyer@foley.com

**FOLEY & LARDNER LLP**  
777 EAST WISCONSIN AVENUE, SUITE. 3800  
MILWAUKEE, WI 53202-5308  
TELEPHONE: (414) 271-2400  
FACSIMILE: (414) 297-4900

RICHARD S. FLORSHEIM, (PRO HAC VICE ADMISSION PENDING)  
rflorsheim@foley.com  
BRIAN A. AKERS, (PRO HAC VICE ADMISSION PENDING)  
bakera@foley.com  
CYNTHIA J. FRANECKI, (PRO HAC VICE ADMISSION PENDING)  
cfranecki@foley.com

**FOLEY & LARDNER LLP**  
3000 K ST., N.W.  
WASHINGTON, DC 20007  
TELEPHONE: 202.872.5300  
FACSIMILE: 202.872.5399

LARRY L. SHATZER, (PRO HAC VICE ADMISSION PENDING)  
lshatzer@foley.com

ATTORNEYS FOR PLAINTIFFS, MEDTRONIC  
VASCULAR, INC.; MEDTRONIC USA, INC.;  
MEDTRONIC, INC., MEDTRONIC VASCULAR  
GALWAY, LTD., AND EVYSIO MEDICAL DEVICES  
ULC

**KATTEN MUCHIN ROSENMAN LLP**  
525 WEST MONROE STREET  
CHICAGO, IL 60661-3883  
TELEPHONE: (312) 902-5200  
FACSIMILE: (312) 902-1061

ERIC C. COHEN, (PRO HAC VICE ADMISSION PENDING)  
eric.cohen@kattenlaw.com

ATTORNEYS FOR PLAINTIFF, EVYSIO MEDICAL  
DEVICES ULC

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COMPLAINT FOR PATENT INFRINGEMENT

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA

MEDTRONIC VASCULAR, INC., a	)	Case No.
Delaware Corporation; MEDTRONIC USA,	)	
INC., a Minnesota Corporation,	)	<b>COMPLAINT FOR PATENT</b>
MEDTRONIC, INC., a Minnesota	)	<b>INFRINGEMENT</b>
Corporation; MEDTRONIC VASCULAR	)	
GALWAY, LTD., an Ireland Corporation; and	)	<b>DEMAND FOR JURY TRIAL</b>
EVYSIO MEDICAL DEVICES ULC, a Nova	)	
Scotia Corporation;	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
ADVANCED CARDIOVASCULAR	)	
SYSTEMS, INC.; a California Corporation;	)	
and GUIDANT SALES CORPORATION, an	)	
Indiana corporation.	)	
	)	
Defendants.	)	

Plaintiffs Medtronic Vascular, Inc., Medtronic USA, Inc., Medtronic, Inc., Medtronic Vascular Galway, Ltd., and Evysio Medical Devices ULC (collectively "Plaintiffs") complain against defendants, Advanced Cardiovascular Systems, Inc. and Guidant Sales Corporation (collectively "Defendants") as follows:

**JURISDICTION AND VENUE**

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code. The Court has federal question jurisdiction under 28 U.S.C. § 1331 and exclusive original jurisdiction under 28 U.S.C. § 1338(a).
2. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b) and 1400(b).

**INTRADISTRICT ASSIGNMENT**

3. This patent action is in an excepted category for Local Rule 3-2(c), Assignment of a Division, and will be assigned on a district wide basis.

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**PARTIES**

4. Plaintiff Medtronic Vascular, Inc. ("Medtronic Vascular") is a corporation organized and existing under the laws of the State of Delaware, with its headquarters and principal place of business in Santa Rosa, California, within this judicial district.

5. Plaintiff Medtronic USA, Inc. ("Medtronic USA") is a corporation organized and existing under the laws of the State of Minnesota, with its principal place of business in Minneapolis, Minnesota.

6. Plaintiff Medtronic, Inc. ("Medtronic") is a corporation organized and existing under the laws of the State of Minnesota, with its principal place of business in Minneapolis, Minnesota.

7. Plaintiff Medtronic Vascular Galway, Ltd. ("Medtronic Galway") is a corporation organized and existing under the laws of the Republic of Ireland, with its principal place of business in Galway, Ireland.

8. Plaintiff Evysio Medical Devices ULC ("Evysio") is a corporation organized and existing under the laws of Nova Scotia, Canada, with its principal place of business in Vancouver, British Colombia.

9. Defendant Advanced Cardiovascular Systems, Inc. ("ACS") is a corporation organized and existing under the laws of the State of California, with its principal place of business in Santa Clara, California, within this judicial district.

10. Defendant Guidant Sales Corporation ("Guidant") is a corporation organized and existing under the laws of the State of Indiana, with its principal place of business in Indianapolis, Indiana. Guidant is an affiliate of ACS.

11. At all material times hereto, Defendants have manufactured, distributed, marketed, offered for sale and sold products, including but not limited to infringing balloon catheters and stents for coronary applications, in this judicial district and elsewhere in the United States.

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**COUNT I – INFRINGEMENT OF U.S. PATENT NO. 6,605,057 B2**

12. Plaintiffs repeat and reallege the allegations of paragraphs 1 through 11 as if set forth herein.

13. U.S. Patent No. 6,605,057 B2 (“the ‘057 Patent”), entitled “Reinforced Monorail Balloon Catheter,” was duly and legally issued on August 12, 2003, by the United States Patent and Trademark Office to Medtronic AVE, Inc., the assignee of the named inventors Thomas K. Fitzmaurice, Paul Gilson, and Patrick J. E. Duane. A true and correct copy of the ‘057 patent is attached hereto as Exhibit A.

14. Medtronic Vascular is the corporation formerly known as Medtronic AVE, Inc., and, as such, is the current owner of the ‘057 Patent.

15. Medtronic Galway is the exclusive licensee of Medtronic Vascular’s rights to make and have made outside of the United States, and of its rights to import, to use, to sublicense others to use, to offer to sell, to sell, and to exclude others who are unlicensed from importing, using, offering to sell, or selling within the United States, products covered by the ‘057 patent.

16. Medtronic USA, is the exclusive licensee of Medtronic Vascular’s rights to use, to sublicense others to use, and to exclude others who are unlicensed from using, within the United States, products covered by the ‘057 Patent.

17. Under the terms of their respective license agreements, each of Medtronic Vascular, Medtronic Galway, and Medtronic USA has the contractual right to exclude others from practicing the inventions claimed in the ‘057 patent and to bring this action.

18. Plaintiffs have complied with the notice provisions of 35 U.S.C. § 287 with respect to the ‘057 patent.

19. Upon information and belief, Defendants have infringed and continue to infringe one or more claims of the ‘057 Patent, directly, contributorily, and/or by inducement, by making, using, selling and/or offering to sell in this country (including in this judicial district), and inducing others to use, without license, certain balloon catheters, including but not limited to Guidant POWERSAIL® Coronary Dilatation Catheters, Guidant HIGHSAIL® Coronary Dilatation Catheters, and Guidant OPENSAIL® Coronary Dilatation Catheters, in violation of

1 35 U.S.C. § 271.

2 20. Further discovery may reveal that Defendants' infringement of the '057 Patent  
3 has been and continues to be willful and carried out with full knowledge of that Patent.

4 21. Medtronic Vascular, Medtronic Galway and Medtronic USA have been and will  
5 continue to be damaged by Defendants' infringement and will be irreparably harmed unless that  
6 infringement is enjoined.

7 **COUNT II – INFRINGEMENT OF U.S. PATENT NO. 6,190,358 B1**

8 22. Plaintiffs repeat and reallege the allegations of paragraphs 1 through 11 as if set  
9 forth herein.

10 23. U.S. Patent No. 6,190,358 B1 ("the '358 Patent"), entitled "Reinforced  
11 Rapid Exchange Balloon Catheter," was duly and legally issued on February 20, 2001, by the  
12 United States Patent and Trademark Office to Medtronic AVE, Inc., the assignee of the named  
13 inventors Thomas K. Fitzmaurice, Patrick J.E. Duane and Paul Gilson. A true and correct copy  
14 of the '358 patent is attached hereto as Exhibit B.

15 24. Medtronic Vascular is the corporation formerly known as Medtronic AVE, Inc.,  
16 and, as such, is the current owner of the '358 Patent.

17 25. Medtronic Galway is the exclusive licensee of Medtronic Vascular's rights to  
18 make and have made outside of the United States, and of its rights to import, to use, to sublicense  
19 others to use, to offer to sell, to sell, and to exclude others who are unlicensed from importing,  
20 using, offering to sell, or selling within the United States, products covered by the '358 Patent.

21 26. Medtronic USA, is the exclusive licensee of Medtronic Vascular's rights to use, to  
22 sublicense others to use, and to exclude others who are unlicensed from using, within the United  
23 States, products covered by the '358 Patent.

24 27. Under the terms of their respective license agreements, each of Medtronic  
25 Vascular, Medtronic Galway, and Medtronic USA has the contractual right to exclude others  
26 from practicing the inventions claimed in the '358 patent and to bring this action.

27 28. Plaintiffs have complied with the notice provisions of 35 U.S.C. § 287 with  
28 respect to the '358 patent.



29. Upon information and belief, Defendants have infringed and continue to infringe one or more claims of the '358 Patent, directly, contributorily, and/or by inducement, by making, using, selling and/or offering to sell in this country (including into this judicial district), and inducing others to use, without license, certain balloon catheters, including but not limited to Guidant POWERSAIL® Coronary Dilatation Catheters, Guidant HIGHSAIL® Coronary Dilatation Catheters, and Guidant OPENSAIL® Coronary Dilatation Catheters, in violation of 35 U.S.C. § 271.

30. Further discovery may reveal that Defendants' infringement of the '358 Patent has been and continues to be willful and carried out with full knowledge of that Patent.

31. Medtronic Vascular, Medtronic Galway and Medtronic USA have been and will continue to be damaged by Defendants' infringement and will be irreparably harmed unless that infringement is enjoined.

### **COUNT III – INFRINGEMENT OF U.S. PATENT NO. 6,858,037 B2**

32. Plaintiffs repeat and reallege the allegations of paragraphs 1 through 11 as if set forth herein

33. U.S. Patent No. 6,858,037 B2 ("the '037 Patent"), entitled "Expandable Stent and Method for Delivery of Same," was duly and legally issued on February 22, 2005, by the United States Patent and Trademark Office to Evysio, the assignee of record of the named inventors Drs. Ian M. Penn and Donald R. Ricci.

34. Evysio is the record owner of the '037 Patent by virtue of an assignment and owns all right and title to the '037 Patent, subject to the licenses it has granted. A true and correct copy of the '037 patent is attached hereto as Exhibit C.

35. Medtronic is the exclusive licensee of the '037 Patent in the field of the human coronary system.

36. Medtronic Galway is the exclusive sublicensee of Medtronic's rights to make and have made outside of the United States, and of its rights to import, to use, to sublicense others to use, to offer to sell, to sell, and to exclude others who are unlicensed from importing, using, offering to sell, or selling within the United States, stents covered by the '037 Patent.

37. Medtronic USA is the exclusive sublicensee of Medtronic Galway's rights to use, to sublicense others to use, and to exclude others who are unlicensed from using, within the United States, stents covered by the '037 Patent.

38. Under the terms of their respective license agreements, each of Medtronic, Medtronic Galway, and Medtronic USA has the contractual right to exclude others from practicing the inventions claimed in the '037 patent and to bring this action.

39. Upon information and belief, Defendants have infringed and continue to infringe one or more claims of the '037 Patent, directly, contributorily, and/or by inducement, by making, using, selling and/or offering to sell in this country (including in this judicial district), and inducing others to use, without a license, stents for coronary applications, including but not limited to Guidant MULTI-LINK VISION® Coronary Stent Systems in violation of 35 U.S.C. § 271.

40. Further discovery may reveal that Defendants' infringement of the '037 Patent has been and continues to be willful and carried out with full knowledge of the '037 Patent.

41. Evysio, Medtronic, Medtronic Galway and Medtronic USA have been and will continue to be damaged by Defendants' infringement of the '037 Patent and will be irreparably harmed unless that infringement is enjoined.

## PRAYER FOR RELIEF

**WHEREFORE, Plaintiffs respectfully request the following relief:**

1. A judgment that Defendants have infringed the '057, '358 and '037 Patents;

2. A preliminary and permanent injunction issued pursuant to 35 U.S.C. § 283, restraining and enjoining Defendants and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from infringement of the, '057, '358 and '037 Patents for the full terms thereof;

3. An award of damages to Plaintiffs including pre-judgment and post-judgment interest, in an amount adequate to compensate for Defendants' infringement of the '057, '358 and '037 Patents, and, if willful infringement is shown, that the damages be trebled pursuant to 35 U.S.C. § 284;

1 4. Costs and expenses in this action;

2 5. A declaration that this is an exceptional case and an award of attorney's fees,  
3 disbursements, and costs of this action pursuant to 35 U.S.C. § 285; and

4 6. Such other and further relief as the Court may deem just and proper.

5 Respectfully submitted,

6 DATE: FEBRUARY 15, 2006

FOLEY & LARDNER LLP

7  
8 By: 

9 Nancy J. Geenen

10 Attorneys for Plaintiffs Medtronic  
11 Vascular, Inc., Medtronic USA, Inc.,  
12 Medtronic, Inc., Medtronic Vascular  
13 Galway, Ltd., and Evysio Medical Devices  
14 ULC  
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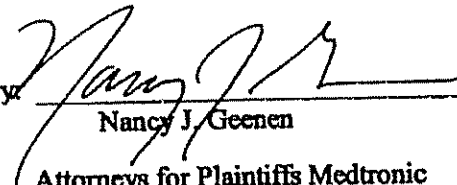
**DEMAND FOR JURY TRIAL**

Plaintiffs respectfully demand a jury trial on all issues so triable.

DATE: FEBRUARY 15, 2006

**FOLEY & LARDNER LLP**

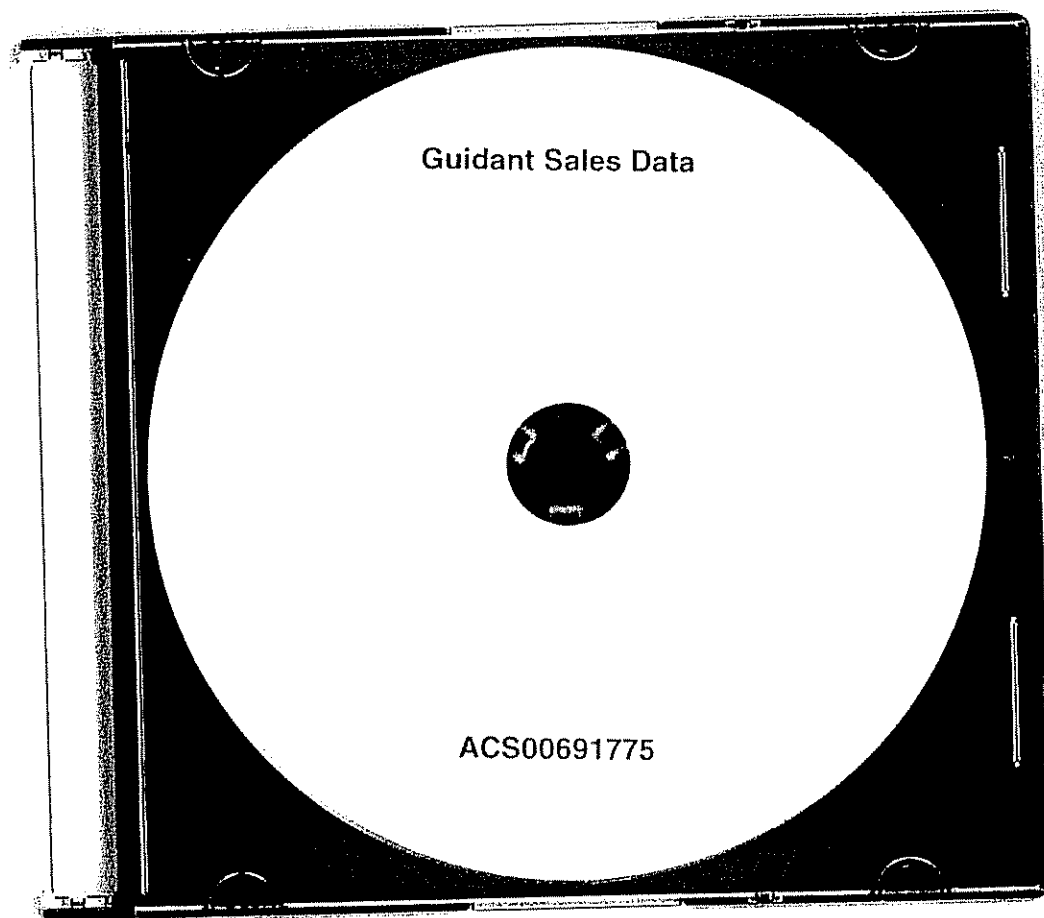
By



Nancy J. Geenen

Attorneys for Plaintiffs Medtronic  
Vascular, Inc., Medtronic USA, Inc.,  
Medtronic, Inc., Medtronic Vascular  
Galway, Ltd., and Evysio Medical Devices  
ULC

# EXHIBIT 20



# EXHIBIT 21



# Morgan Stanley

Industry View  
Attractive

May 7, 2007

## Hosp. Supplies & Medical Technology

### Implications of the CoStar II Failure: Another Blow to J&J

**Conclusion:** With the failure of the CoStar II trial, J&J's stent franchise looks vulnerable to us. In the outer years, we had forecast CoStar sales to comprise around 50% of total DES sales for J&J. As a result of the failed trial, J&J will cease first-generation development efforts with this stent/drug combination and focus on the integration of the CoStar stent platform with J&J's drug/polymer technologies. This is obviously a disappointment for J&J and a modest positive for Abbott and Boston Scientific and, to a lesser extent, Medtronic.

**What's New:** This morning, J&J announced that the CoStar II trial failed to meet its primary endpoint of non-inferiority relative to Boston Scientific's TAXUS stent platform. Full results will be presented at the PCR meeting on May 23. As a result of these data, J&J will no longer be marketing CoStar in Europe and will not pursue FDA approval for this platform in the US.

**Implications:** Before today, we had projected CoStar share of about 3% in 2007, growing to about 13% in 2010. In dollars, this translates into \$128 million in 2007 and \$700 million in 2010. This share will now accrue back to J&J's Cypher, Abbott's Xience, BSX's TAXUS and Promus and Medtronic's Endeavor Platforms. As a result of this event, we are making several changes to our earnings estimates for all four of these companies. We are maintaining our Overweight rating on ABT and our Equal-weight ratings on BSX, JNJ, and MDT.

## MORGAN STANLEY RESEARCH NORTH AMERICA

Morgan Stanley & Co. Incorporated **Glenn Reicin**  
Glenn.Reicin@morganstanley.com  
+1 (1)212 761 6494

**Matt Miksic**  
Matt.Miksic@morganstanley.com  
+1 (1)212 761 6261

**Anthony Yik**  
+1 (1)212 761 3788

**David H Roman**  
+1 (1)212 761 0071

### GICS Sector: Health Care

Strategist's Recommended Weight	14.2%
S&P 500 Weight	12.2%

### Summary of Changes to Company Models

(\$ in millions except per share data)

	2007	2008	2009	2010	2011
<b>Abbott</b>					
<u>EPS</u>					
Prior	\$2.83	\$3.26	\$3.63	\$4.09	\$4.56
Revised	\$2.84	\$3.30	\$3.71	\$4.19	\$4.68
<b>Boston Scientific</b>					
<u>EPS</u>					
Prior	\$0.43	\$0.61	\$0.79	\$1.07	\$1.32
Revised	\$0.45	\$0.66	\$0.85	\$1.13	\$1.37
<b>Johnson &amp; Johnson</b>					
<u>EPS</u>					
Prior	\$4.07	\$4.30	\$4.66	\$5.16	\$5.56
Revised	\$4.05	\$4.24	\$4.57	\$5.05	\$5.45
<b>Medtronic*</b>					
<u>EPS</u>					
Prior	\$2.38	\$2.58	\$2.96	\$3.30	\$3.69
Revised	\$2.38	\$2.60	\$3.00	\$3.35	\$3.75

\*Medtronic numbers are based on an April 30th fiscal year end.  
Lower sales are offset by assumed share repurchases

Source: Morgan Stanley

Morgan Stanley does and seeks to do business with companies covered in its research reports. As a result, investors should be aware that the firm may have a conflict of interest that could affect the objectivity of this report. Investors should consider this report as only a single factor in making their investment decision. Customers of Morgan Stanley in the U.S. can receive independent, third-party research on the company covered in this report, at no cost to them, where such research is available. Customers can access this independent research at [www.morganstanley.com/equityresearch](http://www.morganstanley.com/equityresearch) or can call 1-800-624-2063 to request a copy of this research.

**For analyst certification and other important disclosures, refer to the Disclosure Section.**

# Morgan Stanley

MORGAN STANLEY RESEARCH

May 7, 2007

Hosp Supplies &amp; Medical Technology

## Investment Case

### Summary & Conclusions

This morning, J&J announced that the CoStar II trial failed to meet its primary endpoint of non-inferiority relative to Boston Scientific's TAXUS stent platform. Full results will be presented at the PCR meeting on May 22<sup>nd</sup>. As a result of these data, J&J will no longer be marketing CoStar in Europe and will not pursue FDA approval for this platform in the US.

With the failure of the CoStar II trial, J&J's stent franchise looks incrementally more vulnerable to us. In the outer years, we had forecasted CoStar sales to comprise around 50% of total DES sale for J&J. As a result of the failed trial, J&J will cease first-generation development efforts with this stent/drug combination and focus on the integration of the CoStar stent platform with J&J's drug/polymer technologies. This is obviously a disappointment for J&J and a modest positive for Abbott and Boston Scientific and to a lesser extent Medtronic.

As a result of this event, we are making several changes to our earnings estimates for all four of these companies. We are maintaining our Overweight rating on ABT and our Equal weight ratings on BSX, JNJ and MDT.

**What happened?** CoStar II failed to meet its primary endpoint of demonstration of non-inferiority of CoStar with respect to Major Adverse Coronary Events (MACE) vs Taxus. Total MACE was 11% for CoStar and 6.9% for Taxus. This difference was statistically significant. With respect to secondary endpoints, the data was also similar. If one looks at MACE in just the single-vessel treated patients in the trial, CoStar demonstrated 9.9% MACE vs 6.1%, which was statistically non-inferior and did meet its endpoint. However, if one looks at another secondary endpoint, angiographic late loss, CoStar demonstrated in-segment late loss of 0.48 mm vs 0.15 mm, which was statistically significant. There were no notable differences in stent thrombosis rates between these two platforms.

While a full discussion of all the data will be presented at PCR, management concluded that the dosing was simply too low for CoStar. As such, J&J will discontinue its commercialization efforts with this drug/stent combination stent. The company's efforts in development of a pimecrolimus are also being suspended. This followed some information that was provided to J&J last week regarding this drug from its partner Novartis. Apparently, another licensee of this drug saw sub-optimal data using a different stent platform. Instead, the company will focus mostly on the rapamycin/CoStar combination.

Unfortunately for J&J, this probably will not reach the US market before 2011.

**What about the financial implications?** We have previously factored in 3% WW market share for CoStar in 2007, 5% in 2008, 12% in 2009 and 13% in 2010. In dollars, this translates into \$128 million in 2007, growing to \$700 million by 2010.

At this point, it is safe to assume that the other stents on the market will capture the lost share from CoStar.

For point of reference, we lay out the following template:

- **J&J:** For every \$100 million in stent sales, assuming 75% incremental operating margins and a 23.5% tax rate and 2.950 billion shares, this equates into lost EPS of about \$0.02 per share.
- **ABT:** For every \$100 million in stent sales, assuming 80% incremental operating margins, at 21% tax rate and 1.506 billion shares, this equates into EPS of about \$0.04 per share. This excludes payments made to ABT for sales of Promus from BSX.
- **BSX:** For every \$100 million in stent sales, assuming 83% incremental operating margins on TAXUS and 48% incremental margins in Promus, a 21% tax rate and 1.507 billion shares, we estimate that EPS raises \$0.04 per share.
- **MDT:** For every \$100 million in stent sales, assuming 70% incremental operating margins, a 23% tax rate and 1.167 billion shares, we estimate that EPS rises \$0.05 per share.

For point of reference, our WW 2008 market share estimates were (before this announcement):

10% WW share for BSX's Promus  
23% WW share for BSX's TAXUS  
22% share for J&J's Cypher  
8% share for J&J's CoStar  
15% share for Medtronic's Endeavor  
17% share for ABT's Xience

### Changes to models:

Based on today's announcement, we have made changes to our company models.

# Morgan Stanley

## MORGAN STANLEY RESEARCH

May 7, 2007

Hosp Supplies & Medical Technology

For J&J, we have lowered our EPS estimates for 2007–2011 by \$0.02, \$0.06, \$0.09, \$0.11, and \$0.11. Our revised EPS estimates for 2007–2011 are \$4.05, \$4.24, \$4.57, \$5.05, and \$5.45. With this news, we expect that share will deteriorate over time since the Costar/Rapamycin combination will not hit the US market before 2011. There should be some opportunity in Europe before that time, but without seeing any clinical data, it is hard to dial this into our estimates. Other issues that investors need to be aware of for this month are Thursday's ODAC panel meeting on EPO and a decision in the courts regarding the continued exclusivity of ACIPHEX patents.

For ABT, we have raised our EPS estimates for 2007–2011 by \$0.01, \$0.04, \$0.08, \$0.10, and \$0.12. Our revised EPS estimates for 2007–2011 are \$2.84, \$3.30, \$3.71, \$4.19, and \$4.68. Abbott benefits from its own sales as well as payments on Promus sales from BSX. Over time, more benefit will accrue to Abbott since we have them gaining share over time. We continue to find this name the best DES investment vehicle at this time.

For BSX, we have raised our EPS estimates for 2007–2011 by \$0.02, \$0.05, \$0.06, \$0.06, and \$0.05. Our revised EPS estimates for 2007–2011 are \$0.45, \$0.66, \$0.85, \$1.13, and \$1.37. The benefit from this news declines over time since we have modeled for the company to lose share. As such, this does not impact the long-term growth rate. While this is good news for the company, we still think it is tough to understand what the true earnings power of this company is at this time.

For MDT, we have raised our EPS estimates for *fiscal* 2008–2011 by \$0.02, \$0.04, \$0.05, and \$0.06. Our revised EPS estimates for fiscal 2007–2011 are \$2.60, \$3.00, \$3.35, and \$3.75. While DES will be an important growth driver for the company, we continue to be concerned about the company's health and sustainability of growth and share in CRM and Spine.

Due to these changes, we now peg 2008 worldwide market shares as follows:

- 11% WW share for BSX's Promus
- 24% WW share for BSX's TAXUS
- 21% share for J&J's Cypher
- 16% share for Medtronic's Endeavor
- 23% share for ABT's Xience

### Exhibit 1

### Summary of Changes to Company Models

(\$ in millions except per share data)

	2007	2008	2009	2010	2011	CAGR
<b>Abbott</b>						
<u>Sales</u>						
Prior	\$22.283	\$24.472	\$26.537	\$29.051	\$31.396	8.9%
Revised	22.292	24.598	26.769	29.336	31.681	9.2%
<u>EPS</u>						
Prior	\$2.83	\$3.26	\$3.63	\$4.09	\$4.56	12.7%
Revised	\$2.84	\$3.30	\$3.71	\$4.19	\$4.68	13.3%
<b>Boston Scientific</b>						
<u>Sales</u>						
Prior	\$8.571	\$8.990	\$9.587	\$10.491	\$11.400	7.4%
Revised	8.615	9.122	9.765	10.690	11.585	7.7%
<u>EPS</u>						
Prior	\$0.43	\$0.61	\$0.79	\$1.07	\$1.32	32.2%
Revised	\$0.45	\$0.66	\$0.85	\$1.13	\$1.37	31.9%
<b>Johnson &amp; Johnson</b>						
<u>Sales</u>						
Prior	\$60.721	\$62.698	\$65.484	\$70.269	\$73.887	5.0%
Revised	60.615	62.353	64.947	69.644	73.300	4.9%
<u>EPS</u>						
Prior	\$4.07	\$4.30	\$4.66	\$5.16	\$5.56	8.1%
Revised	\$4.05	\$4.24	\$4.57	\$5.05	\$5.45	7.7%
<b>Medtronic*</b>						
<u>Sales</u>						
Prior	\$12.241	\$13.280	\$14.822	\$16.298	\$17.843	9.9%
Revised	12.241	13.319	14.906	16.416	17.974	10.1%
<u>EPS</u>						
Prior	\$2.38	\$2.58	\$2.96	\$3.30	\$3.69	11.6%
Revised	\$2.38	\$2.60	\$3.00	\$3.35	\$3.75	12.1%

\*Medtronic numbers are based on an April 30th fiscal year end

Lower sales are offset by assumed share repurchases

Source: Morgan Stanley

Morgan Stanley & Co. Incorporated ("Morgan Stanley") is acting as financial advisor to Abbott Laboratories ("Abbott") in its announced proposed sale of its core laboratory diagnostics business included in the Abbott Diagnostics Division and Abbott Point of Care to General Electric Company.

Abbott has agreed to pay fees to Morgan Stanley for its financial services, including transaction fees that are subject to the consummation of the proposed transaction.

Please refer to the notes at the end of this report.

Morgan Stanley

MORGAN STANLEY RESEARCH

May 7, 2007

Hosp. Supplies &amp; Medical Technology

## Exhibit 2

## Coronary Stents

## Estimated Worldwide Market, 2000-2010E

	2000	2001	2002A	2003A	2004A	2005A	2006A	2007E	2008E	2009E	2010E
No. of Stent Procedures (000)	1103	1266	1605	1836	2045	2230	2393	2436	2546	2704	2861
% change	17%	15%	27%	14%	11%	9%	7%	2%	5%	6%	6%
Stents per Procedure	1.5	1.5	1.4	1.4	1.5	1.6	1.6	1.6	1.6	1.6	1.5
Price Per Stent	\$1.345	\$1.185	\$1.069	\$1.305	\$1.698	\$1.726	\$1.625	\$1.443	\$1.419	\$1.363	\$1.289
% change	-6%	-12%	-10%	22%	30%	2%	-6%	-11%	-2%	-4%	-5%
Revenue Per Procedure	\$2.084	\$1.791	\$1.481	\$1.830	\$2.507	\$2.740	\$2.622	\$2.316	\$2.222	\$2.116	\$1.957
% change	-8%	-14%	-17%	24%	37%	9%	-4%	-12%	-4%	-5%	-8%
Total Worldwide Stent Market (\$ millions)	\$2,300	\$2,269	\$2,377	\$3,360	\$5,125	\$6,110	\$6,273	\$5,641	\$5,658	\$5,722	\$5,599
Stocking (\$ millions)	(\$59)	\$17	(\$5)	\$0	\$25	\$0	\$0	\$0	\$0	\$0	\$0
Total Worldwide Stent Sales (\$ millions)	\$2,241	\$2,286	\$2,372	\$3,360	\$5,150	\$6,110	\$6,273	\$5,641	\$5,658	\$5,722	\$5,599
% change	5%	2%	4%	42%	53%	19%	3%	-10%	0%	1%	-2%
<b>WW Revenues By Competitor (\$ millions)</b>											
Boston Scientific	\$429	\$344	\$318	\$527	\$2,351	\$2,694	\$2,503	\$2,224	\$1,909	\$1,618	\$1,551
Abbott/Guidant	\$821	\$819	\$874	\$783	\$440	\$332	\$362	\$682	\$1,456	\$2,028	\$2,089
Johnson & Johnson	\$260	\$471	\$687	\$1,581	\$1,959	\$2,635	\$2,634	\$1,839	\$1,044	\$704	\$534
Medtronic	\$638	\$580	\$394	\$360	\$335	\$347	\$510	\$661	\$970	\$1,076	\$1,079
Conor	\$0	\$0	\$0	\$0	\$0	\$0	\$65	\$15	\$0	\$0	\$0
Other	\$93	\$72	\$99	\$109	\$65	\$100	\$202	\$220	\$278	\$296	\$347
<b>WW Market Shares</b>											
Boston Scientific	19%	15%	13%	16%	46%	44%	40%	39%	34%	28%	28%
Abbott/Guidant	37%	36%	37%	23%	9%	5%	6%	12%	26%	35%	37%
Johnson & Johnson	12%	21%	29%	47%	38%	43%	42%	33%	18%	12%	10%
Medtronic	28%	25%	17%	11%	7%	6%	8%	12%	17%	19%	19%
Conor	0%	0%	0%	0%	0%	0%	1%	0%	0%	0%	0%
Other	4%	3%	4%	3%	1%	2%	3%	4%	5%	5%	6%

E - Morgan Stanley Research Estimate

Source - Morgan Stanley Research



## MORGAN STANLEY RESEARCH

May 7, 2007

Hosp Supplies &amp; Medical Technology

## Exhibit 3

## Coronary Stents

## Estimated United States Market, 2000-2010E

	2000	2001	2002	2003	2004	2005	2006	2007E	2008E	2009E	2010E
No. of PTCA Procedures (000)	770	810	850	920	980	1030	1,092	1,039	1,039	1,081	1,124
% change	6%	5%	5%	8%	7%	5%	6%	-5%	0%	4%	4%
% of PTCA Procedures Using Stents	81%	85%	88%	90%	90%	90%	89%	87%	88%	89%	89%
Number of Stent Procedures (000)	624	690	751	828	882	932	972	908	915	962	1001
% change	15%	11%	9%	10%	7%	6%	4%	-7%	1%	5%	4%
% of Stent Procedures Using Bare Metal Stents	100%	100%	100%	67%	21%	12%	18%	31%	27%	28%	21%
% of Stent Procedures Using Drug-Eluting Stents	0%	0%	0%	33%	80%	88%	83%	70%	73%	75%	79%
<b>US Bare Metal Stent Market</b>											
Number of Bare Metal Stent Procedures (000)	624	690	751	557	181	113	170	277	247	241	210
Stents Per Procedure	1.8	1.7	1.7	1.6	1.7	1.7	1.7	1.7	1.6	1.5	1.5
Price Per Bare Metal Stent	\$1,350	\$1,202	\$1,121	\$895	\$950	\$915	\$850	\$790	\$735	\$635	\$540
Total Revenues Per Procedure	\$2,381	\$2,073	\$1,861	\$1,468	\$1,644	\$1,597	\$1,479	\$1,375	\$1,139	\$978	\$826
Total US Bare Metal Stent Market (\$ millions)	\$1,485	\$1,431	\$1,397	\$818	\$297	\$180	\$252	\$381	\$281	\$235	\$174
Stocking (\$ millions)	(\$59)	\$21	(\$5)	\$0	\$1	\$0	\$0	\$0	\$0	\$0	\$0
Total US Bare Metal Stent Sales (\$ millions)	\$1,426	\$1,452	\$1,392	\$818	\$298	\$180	\$252	\$381	\$281	\$235	\$174
% Change	1%	2%	-1%	-11%	-64%	-40%	-40%	51%	-26%	-16%	-26%
<b>US Drug-Eluting Stent Market</b>											
Number of Drug-Eluting Stent Procedures (000)	0	0	0	393	1100	1317	1297	971	1032	1113	1216
Stents Per Procedure				1.5	1.6	1.6	1.6	1.5	1.5	1.5	1.5
Price Per Drug-Eluting Stent				\$2,800	\$2,525	\$2,345	\$2,228	\$2,161	\$2,095	\$1,985	\$1,885
Total Revenues Per Procedure				\$4,060	\$3,962	\$3,771	\$3,604	\$3,323	\$3,237	\$3,061	\$2,899
Total US Drug-Eluting Stent Market (\$ millions)				\$1,100	\$2,778	\$3,088	\$2,889	\$2,098	\$2,161	\$2,209	\$2,292
Stocking (\$ millions)				\$0	\$11	\$0	\$0	\$0	\$0	\$0	\$0
Total US Drug-Eluting Stent Sales (\$ millions)				\$1,100	\$2,789	\$3,088	\$2,889	\$2,098	\$2,161	\$2,209	\$2,292
% Change					154%	11%	-6%	-27%	3%	2%	4%
<b>Total US Stent Market</b>											
Total Number of Stent Procedures (000)	624	690	751	828	882	932	972	908	915	962	1001
Stents Per Procedure	1.8	1.7	1.7	1.6	1.6	1.6	1.6	1.6	1.5	1.5	1.5
Average Price Per Stent	\$1,350	\$1,202	\$1,121	\$1,518	\$2,202	\$2,472	\$1,987	\$1,743	\$1,728	\$1,648	\$1,603
Total Revenues Per Procedure	\$2,381	\$2,073	\$1,861	\$5,528	\$5,605	\$5,367	\$5,083	\$4,697	\$4,376	\$4,039	\$3,725
Total US Stent Market (\$ millions)	\$1,485	\$1,431	\$1,397	\$1,917	\$3,075	\$3,268	\$3,140	\$2,479	\$2,443	\$2,444	\$2,465
Stocking (\$ millions)	(\$59)	\$21	(\$5)	\$0	\$12	\$0	\$0	\$0	\$0	\$0	\$0
Total US Stent Sales (\$ millions)	\$1,426	\$1,452	\$1,392	\$1,917	\$3,087	\$3,268	\$3,140	\$2,479	\$2,443	\$2,444	\$2,465
% Change	1%	2%	-1%	38%	61%	0%	-4%	-21%	-1%	0%	1%
<b>Total US Stent Sales By Competitor</b>											
	2000	2001	2002	2003A	2004A	2005A	2006A	2007E	2008E	2009E	2010E
<b>Bare Metal</b>	\$1,426	\$1,452	\$1,392	\$1,918	\$3,087	\$3,268	\$3,142	\$2,479	\$2,442	\$2,444	\$2,466
Boston Scientific - Liberte	\$1,426	\$1,452	\$1,392	\$818	\$298	\$180	\$253	\$381	\$281	\$235	\$174
Gardant	\$248	\$182	\$180	\$213	\$59	\$36	\$52	\$83	\$66	\$49	\$20
Abbott/Guidant	\$594	\$585	\$576	\$402	\$162	\$117	\$159	\$235	\$160	\$130	\$97
Johnson & Johnson	\$148	\$309	\$387	\$75	\$18	\$0	\$0	\$0	\$0	\$0	\$0
Medtronic	\$418	\$356	\$197	\$118	\$59	\$27	\$42	\$63	\$55	\$56	\$57
Other	\$18	\$20	\$52	\$10	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<b>Drug-Eluting</b>				\$1,100	\$2,789	\$3,088	\$2,889	\$2,098	\$2,161	\$2,209	\$2,292
Boston Scientific - Total				\$0	\$1,570	\$1,764	\$1,561	\$1,082	\$767	\$652	\$680
Boston Scientific - Promus				\$0	\$0	\$0	\$0	\$0	\$271	\$369	\$412
Boston Scientific - TAXUS Liberte				\$0	\$1,570	\$1,764	\$1,561	\$1,082	\$496	\$283	\$268
Johnson & Johnson				\$1,100	\$1,219	\$1,324	\$1,328	\$882	\$495	\$255	\$236
Medtronic				\$0	\$0	\$0	\$0	\$134	\$320	\$417	\$478
Abbott - Nience				\$0	\$0	\$0	\$0	\$0	\$579	\$885	\$898
Conor				\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<b>US Stent Market Shares</b>											
<b>Bare Metal</b>	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
Boston Scientific - Liberte	17%	13%	13%	26%	20%	20%	21%	22%	23%	21%	11%
Gardant	42%	40%	41%	49%	54%	65%	63%	62%	57%	55%	56%
Johnson & Johnson	10%	21%	28%	9%	6%	0%	0%	0%	0%	0%	0%
Medtronic	29%	25%	14%	14%	20%	15%	17%	17%	20%	24%	33%
Other	1%	1%	4%	1%	0%	0%	0%	0%	0%	0%	0%
<b>Drug-Eluting</b>				100%	100%	100%	100%	100%	100%	100%	100%
Boston Scientific - Total				0%	56%	57%	54%	52%	35%	30%	30%
Boston Scientific - Promus				0%	0%	0%	0%	0%	13%	17%	18%
Boston Scientific - TAXUS Liberte				0%	56%	57%	54%	52%	23%	13%	12%
Johnson & Johnson				100%	44%	43%	46%	42%	23%	12%	10%
Medtronic				0%	0%	0%	0%	6%	15%	19%	21%
Abbott - Nience				0%	0%	0%	0%	0%	27%	40%	39%
Conor				0%	0%	0%	0%	0%	0%	0%	0%

E - Morgan Stanley Research Estimate

Source: Morgan Stanley Research



## MORGAN STANLEY RESEARCH

May 7, 2007

Hosp Supplies &amp; Medical Technology

## Exhibit 4

## Coronary Stents

## Estimated International Market, 2000-2010E

	2000	2001	2002	2003	2004	2005	2006	2007E	2008E	2009E	2010E
No. of PTCA Procedures (000)	702	804	1029	1208	1324	1448	1584	1691	1806	1929	2059
% change	11%	15%	28%	17%	10%	9%	9%	7%	7%	7%	7%
% of PTCA Procedures Using Stents	68%	72%	83%	83%	88%	90%	90%	90%	90%	90%	90%
Number of Stent Procedures (000)	480	576	855	1008	1163	1299	1421	1528	1632	1742	1861
% change	19%	20%	48%	18%	13%	12%	9%	8%	7%	7%	7%
% of Stent Procedures Using Bare Metal Stents	100%	100%	97%	75%	54%	37%	30%	31%	28%	25%	23%
% of Stent Procedures Using Drug-Eluting Stents	0%	0%	3%	25%	46%	63%	70%	69%	72%	75%	77%
<b>OUS Bare Metal Stent Market</b>											
Number of Bare Metal Stent Procedures (000)	480	576	832	760	629	486	432	476	449	440	435
Stents Per Procedure	1.3	1.3	1.1	1.3	1.4	1.6	1.6	1.6	1.5	1.4	1.4
Price Per Bare Metal Stent	\$1,335	\$1,147	\$925	\$971	\$888	\$805	\$763	\$694	\$641	\$549	\$394
Total Revenues Per Procedure	\$1,698	\$1,439	\$1,060	\$1,224	\$1,235	\$1,302	\$1,201	\$1,114	\$963	\$764	\$535
Total OUS Bare Metal Stent Market (\$ millions)	\$815	\$838	\$906	\$946	\$803	\$638	\$524	\$528	\$431	\$335	\$232
Stocking (\$ millions)	\$0	(\$4)	\$1	\$0	\$7	\$0	\$0	\$0	\$0	\$0	\$0
Total OUS Bare Metal Stent Sales (\$ millions)	\$815	\$834	\$907	\$946	\$810	\$638	\$524	\$528	\$431	\$335	\$232
% Change	12%	2%	9%	4%	-14%	-21%	-18%	1%	-18%	-22%	-31%
<b>OUS Drug-Eluting Stent Market</b>											
Number of Drug-Eluting Stent Procedures (000)	0	0	22	248	534	813	989	1051	1182	1303	1426
Stents Per Procedure			1.1	1.3	1.4	1.5	1.6	1.6	1.6	1.6	1.6
Price Per Drug-Eluting Stent			\$1,630	\$1,680	\$1,703	\$1,763	\$1,655	\$1,578	\$1,487	\$1,410	\$1,311
Total Revenues Per Procedure			\$1,828	\$2,000	\$2,333	\$2,691	\$2,658	\$2,539	\$2,386	\$2,276	\$2,036
Total OUS Drug-Eluting Stent Market (\$ millions)			\$74	\$497	\$1,247	\$2,204	\$2,609	\$2,634	\$2,784	\$2,944	\$2,901
Stocking (\$ millions)			\$0	\$0	\$6	\$0	\$0	\$0	\$0	\$0	\$0
Total OUS Drug-Eluting Stent Sales (\$ millions)			\$74	\$497	\$1,253	\$2,204	\$2,609	\$2,634	\$2,784	\$2,944	\$2,901
% Change				571%	152%	70%	18%	1%	6%	6%	-1%
<b>Total OUS Stent Market</b>											
Total Number of Stent Procedures (000)	480	576	855	1008	1163	1299	1421	1528	1632	1742	1861
Stents Per Procedure	1.3	1.3	1.1	1.3	1.4	1.6	1.6	1.6	1.6	1.6	1.5
Average Price Per Stent	\$1,335	\$1,147	\$944	\$1,126	\$1,262	\$1,405	\$1,383	\$1,302	\$1,254	\$1,193	\$1,097
Total Revenues Per Procedure	\$1,698	\$1,439	\$1,080	\$1,416	\$1,743	\$2,192	\$2,208	\$2,094	\$1,977	\$1,859	\$1,654
Total OUS Stent Market (\$ millions)	\$815	\$838	\$980	\$1,442	\$2,050	\$2,842	\$3,133	\$3,163	\$3,216	\$3,279	\$3,134
Stocking (\$ millions)	\$0	(\$4)	\$1	\$0	\$13	\$0	\$0	\$0	\$0	\$0	\$0
Total OUS Stent Sales (\$ millions)	\$815	\$834	\$981	\$1,442	\$2,063	\$2,842	\$3,133	\$3,163	\$3,216	\$3,279	\$3,134
% Change	12%	2%	18%	47%	43%	38%	10%	1%	2%	2%	-4%
<b>Total OUS Stent Sales By Competitor</b>											
	2000	2001	2002	2003	2004	2005	2006	2007E	2008E	2009E	2010E
<b>Bare Metal</b>	\$815	\$834	\$907	\$1,442	\$2,063	\$2,840	\$3,134	\$3,162	\$3,215	\$3,278	\$3,134
Boston Scientific	\$181	\$162	\$138	\$115	\$148	\$99	\$93	\$125	\$105	\$65	\$45
Abbott/Guidant	\$227	\$234	\$298	\$381	\$278	\$215	\$163	\$198	\$160	\$145	\$101
Johnson & Johnson	\$112	\$162	\$230	\$130	\$78	\$50	\$14	\$15	\$10	\$10	\$6
Medtronic	\$220	\$224	\$197	\$242	\$276	\$241	\$198	\$150	\$121	\$85	\$50
Other	\$75	\$52	\$43	\$80	\$30	\$33	\$57	\$40	\$35	\$30	\$30
<b>Drug-Eluting</b>	\$74	\$494	\$1,253	\$2,202	\$2,202	\$2,609	\$2,634	\$2,784	\$2,943	\$2,943	\$2,902
Boston Scientific - Total	\$0	\$199	\$574	\$795	\$795	\$797	\$934	\$971	\$852	\$806	\$806
Boston Scientific - Promus	\$0	\$0	\$0	\$0	\$0	\$0	\$112	\$267	\$410	\$410	\$410
Boston Scientific - TAXUS Liberté	\$0	\$199	\$574	\$795	\$795	\$797	\$822	\$704	\$442	\$394	\$394
Johnson & Johnson	\$70	\$276	\$644	\$1,261	\$1,292	\$942	\$942	\$539	\$439	\$292	\$292
Medtronic	\$0	\$0	\$0	\$0	\$79	\$270	\$314	\$474	\$518	\$494	\$494
Abbott - Xience	\$0	\$0	\$0	\$0	\$0	\$40	\$249	\$357	\$868	\$993	\$993
Conor (End-user)	\$0	\$0	\$0	\$0	\$0	\$65	\$15	\$0	\$0	\$0	\$0
Other	\$4	\$19	\$35	\$35	\$67	\$145	\$180	\$243	\$266	\$317	\$317
<b>OUS Stent Market Shares</b>											
<b>Bare Metal</b>	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
Boston Scientific	22%	19%	15%	12%	18%	16%	18%	24%	24%	19%	19%
Guidant	28%	28%	33%	40%	34%	34%	31%	38%	37%	43%	43%
Johnson & Johnson	14%	19%	25%	14%	10%	8%	3%	3%	2%	3%	3%
Medtronic	27%	27%	22%	26%	34%	38%	38%	28%	28%	25%	22%
Other	9%	6%	5%	8%	4%	3%	11%	8%	8%	9%	13%
<b>Drug-Eluting</b>			100%	100%	100%	100%	100%	100%	100%	100%	100%
Boston Scientific - Total			0%	40%	46%	36%	31%	35%	29%	28%	28%
Boston Scientific - Promus			0%	0%	0%	0%	0%	4%	10%	14%	16%
Boston Scientific - TAXUS Liberté			0%	40%	46%	36%	31%	25%	15%	12%	12%
Johnson & Johnson			95%	56%	51%	57%	50%	36%	19%	15%	10%
Medtronic			0%	0%	0%	4%	10%	12%	17%	18%	17%
Abbott - Xience			0%	0%	0%	0%	2%	9%	20%	29%	34%
Conor (End-user)			0%	0%	0%	0%	2%	1%	0%	0%	0%
Other			5%	4%	3%	3%	6%	7%	9%	9%	11%

E - Morgan Stanley Research Estimate

Source: Morgan Stanley Research





## MORGAN STANLEY RESEARCH

May 7, 2007

Hosp Supplies &amp; Medical Technology

## Exhibit 5

JAPAN Stent Market											
No. of PTCA Procedures Japan (000)	132	142	150	158	164	172	181	190	199	209	220
% change	9%	8%	6%	5%	4%	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%
% of PTCA Procedures Using Stents	60%	68%	72%	67%	72%	80%	80%	85%	85%	85%	85%
Number of Stent Procedures Japan (000)	79	97	107	105	117	138	144	161	169	178	187
% change	22%	23%	11%	-2%	13%	16%	5%	12%	5%	5%	5%
% of Stent Procedures Using Bare Metal Stents, Japan	100%	100%	100%	100%	67%	28%	17%	20%	15%	10%	9%
% of Stent Procedures Using Drug-Eluting Stents, Japan	0%	0%	0%	0%	34%	72%	84%	80%	85%	90%	91%
Japan Bare Metal Stent Market											
Number of Bare Metal Stent Procedures (000)	79	97	107	105	71	39	24	32	25	17	16
Stents Per Procedure	1.1	1.4	1.4	1.4	1.6	1.7	1.7	1.6	1.5	1.4	1.4
Price Per Bare Metal Stent	\$2,238	\$1,728	\$1,700	\$2,160	\$2,025	\$2,025	\$1,725	\$1,725	\$1,750	\$1,750	\$1,663
Total Revenues Per Procedure	\$2,865	\$2,385	\$2,380	\$2,888	\$3,329	\$3,503	\$3,350	\$2,984	\$2,538	\$2,363	\$2,244
Total Japan Bare Metal Stent Market (\$ millions)	\$226	\$231	\$256	\$303	\$263	\$135	\$80	\$96	\$64	\$40	\$36
Stocking (\$ millions)	\$0	\$0	\$5	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Total Japan Bare Metal Stent Sales (\$ millions)	\$226	\$231	\$261	\$303	\$263	\$135	\$80	\$96	\$64	\$40	\$36
% Change	23%	2%	13%	16%	-13%	-49%	-41%	21%	-33%	-37%	-11%
Japan Drug-Eluting Stent Market											
Number of Drug-Eluting Stent Procedures (000)	0	0	0	0	40	99	120	129	144	161	171
Stents Per Procedure					1.4	1.6	1.5	1.5	1.5	1.5	1.5
Price Per Drug-Eluting Stent					\$3,300	\$3,300	\$3,135	\$3,135	\$2,978	\$2,978	\$2,829
Total Revenues Per Procedure					\$4,620	\$5,346	\$4,740	\$4,561	\$4,333	\$4,584	\$4,366
Total Japan Drug-Eluting Stent Market (\$ millions)					\$184	\$530	\$570	\$588	\$623	\$736	\$745
Stocking (\$ millions)					\$0	\$0	\$0	\$0	\$0	\$0	\$0
Total Japan Drug-Eluting Stent Sales (\$ millions)					\$184	\$530	\$570	\$588	\$623	\$736	\$745
% Change					170%	8%	1%	6%	18%	1%	
Total Japan Stent Market											
Total Number of Stent Procedures (000)	79	97	107	105	117	138	144	161	169	178	187
Stents Per Procedure	1.1	1.4	1.4	1.4	1.6	1.7	1.5	1.5	1.5	1.5	1.5
Average Price Per Stent	\$2,238	\$1,728	\$1,700	\$2,160	\$2,452	\$2,943	\$2,935	\$2,893	\$2,794	\$2,860	\$2,729
Total Revenues Per Procedure	\$2,865	\$2,385	\$2,380	\$2,888	\$3,762	\$4,830	\$4,511	\$4,246	\$4,664	\$4,370	\$4,183
Total OUS Stent Market (\$ millions)	\$226	\$231	\$256	\$303	\$446	\$665	\$649	\$684	\$688	\$777	\$781
Stocking (\$ millions)	\$0	\$0	\$5	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Total OUS Stent Sales (\$ millions)	\$226	\$231	\$261	\$303	\$446	\$665	\$649	\$684	\$688	\$777	\$781
% Change	23%	2%	13%	16%	49%	47%	-2%	5%	1%	13%	1%
Total Japan Stent Sales By Competitor											
Bare Metal			\$261	\$303	\$453	\$665	\$650	\$684	\$687	\$776	\$781
Boston Scientific			\$261	\$303	\$263	\$135	\$80	\$96	\$64	\$40	\$36
Abbott/Guidant			\$40	\$23	\$65	\$15	\$15	\$11	\$10	\$10	\$10
Johnson & Johnson			\$116	\$190	\$85	\$40	\$10	\$25	\$20	\$15	\$11
Medtronic			\$75	\$50	\$38	\$10	\$0	\$0	\$0	\$0	\$0
Other			\$25	\$13	\$70	\$65	\$48	\$40	\$21	\$5	\$5
Drug-Eluting			\$0	\$0	\$190	\$530	\$570	\$588	\$623	\$736	\$745
Boston Scientific - Total			\$0	\$0	\$0	\$0	\$0	\$230	\$360	\$326	\$230
Boston Scientific - Promus			\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$77	\$101
Boston Scientific - TAXUS Liberte			\$0	\$0	\$0	\$0	\$0	\$230	\$360	\$149	\$109
Johnson & Johnson			\$0	\$0	\$120	\$330	\$570	\$358	\$151	\$134	\$67
Medtronic			\$0	\$0	\$0	\$0	\$0	\$0	\$110	\$146	\$111
Abbott - Xience			\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$230	\$235
Coron (End-User)			\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Other			\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$62
JP Stent Market Shares											
Bare Metal				100%	100%	100%	100%	100%	100%	100%	100%
Boston Scientific				8%	23%	13%	12%	11%	16%	25%	28%
Guidant				63%	32%	30%	13%	26%	31%	38%	31%
Johnson & Johnson				16%	14%	7%	9%	0%	0%	0%	0%
Medtronic				11%	27%	48%	69%	42%	33%	13%	14%
Other				2%	2%	4%	9%	21%	20%	25%	28%
Drug-Eluting				NM	100%	100%	100%	100%	100%	100%	92%
Boston Scientific - Total				NM	0%	0%	0%	39%	58%	31%	28%
Boston Scientific - Promus				NM	0%	0%	0%	0%	0%	10%	14%
Boston Scientific - TAXUS Liberte				NM	0%	0%	0%	39%	58%	20%	15%
Johnson & Johnson				NM	100%	100%	100%	61%	25%	18%	9%
Medtronic				NM	0%	0%	0%	0%	18%	20%	15%
Abbott - Xience				NM	0%	0%	0%	0%	0%	11%	40%
Coron (End-User)				NM	0%	0%	0%	0%	0%	0%	0%
Other				NM	0%	0%	0%	0%	0%	0%	8%

E - Morgan Stanley Research Estimate

Source: Morgan Stanley Research





## MORGAN STANLEY RESEARCH

May 7, 2007

Hosp. Supplies &amp; Medical Technology

Exhibit 6											
EUROPE & REST OF WORLD Stent Market											
No. of PTCA Procedures Europe & Rest of World (000)	2000	2001	2002	2003A	2004A	2005A	2006A	2007E	2008E	2009E	2010E
% change	57%	66%	87%	105%	116%	127%	140%	150%	160%	171%	184%
% of PTCA Procedures Using Stents	70%	72%	85%	86%	90%	91%	91%	91%	91%	91%	91%
Number of Stent Procedures Europe & Rest of World (000)	2000	2001	2002	2003A	2004A	2005A	2006A	2007E	2008E	2009E	2010E
% change	19%	20%	56%	21%	16%	11%	10%	7%	7%	7%	7%
% of Stent Procedures Using Bare Metal Stents, Europe & ROW	100%	100%	97%	73%	53%	39%	32%	33%	29%	27%	25%
% of Stent Procedures Using Drug-Eluting Stents, Europe & ROW	0%	0%	3%	28%	47%	62%	68%	68%	71%	73%	75%
Europe & Rest of World Bare Metal Stent Market											
Number of Bare Metal Stent Procedures (000)	2000	2001	2002	2003A	2004A	2005A	2006A	2007E	2008E	2009E	2010E
Stents Per Procedure	1.3	1.2	1.1	1.2	1.4	1.6	1.6	1.6	1.5	1.4	1.4
Price Per Bare Metal Stent	\$1.157	\$1.029	\$810	\$790	\$725	\$700	\$695	\$605	\$575	\$500	\$345
Total Revenues Per Procedure	\$1.469	\$1.266	\$897	\$981	\$982	\$1.126	\$1.088	\$973	\$865	\$698	\$469
Total Europe & Rest of World Bare Metal Stent Market (\$ millions)	\$589	\$607	\$650	\$642	\$540	\$503	\$445	\$432	\$367	\$295	\$196
Stocking (\$ millions)	\$0	(\$4)	(\$5)	\$0	\$7	\$0	\$0	\$0	\$0	\$0	\$0
Total Europe & Rest of World Bare Metal Stent Sales (\$ millions)	\$589	\$603	\$646	\$642	\$547	\$503	\$445	\$432	\$367	\$295	\$196
% Change	9%	2%	7%	-1%	-15%	-8%	-12%	-3%	-15%	-20%	-33%
Europe & Rest of World Drug-Eluting Stent Market											
Number of Drug-Eluting Stent Procedures (000)	2000	2001	2002	2003A	2004A	2005A	2006A	2007E	2008E	2009E	2010E
Stents Per Procedure	1.1	1.1	1.1	1.3	1.4	1.5	1.6	1.6	1.6	1.6	1.6
Price Per Drug-Eluting Stent	\$1.650	\$1.600	\$1.600	\$1.575	\$1.550	\$1.450	\$1.360	\$1.280	\$1.190	\$1.105	\$1.105
Total Revenues Per Procedure	\$1.828	\$1.800	\$1.800	\$2.153	\$2.345	\$2.348	\$2.218	\$2.081	\$1.933	\$1.718	\$1.718
Total Europe & Rest of World Drug-Eluting Stent Market (\$ millions)	\$74	\$497	\$1.063	\$1.675	\$2.039	\$2.046	\$2.161	\$2.207	\$2.157	\$2.157	\$2.157
Stocking (\$ millions)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Total Europe & Rest of World Drug-Eluting Stent Sales (\$ millions)	\$74	\$497	\$1.063	\$1.675	\$2.039	\$2.046	\$2.161	\$2.207	\$2.157	\$2.157	\$2.157
% Change	NM	NM	NM	114%	58%	22%	0%	6%	2%	-2%	-2%
Total Europe & Rest of World Stent Sales By Competitor											
Bare Metal	\$645	\$547	\$503	\$445	\$432	\$367	\$295	\$196			
Boston Scientific	\$92	\$83	\$84	\$78	\$114	\$95	\$55	\$35			
Guidant	\$191	\$193	\$175	\$153	\$173	\$140	\$130	\$90			
Johnson & Johnson	\$80	\$40	\$40	\$14	\$15	\$10	\$10	\$6			
Medtronic	\$209	\$206	\$176	\$150	\$110	\$100	\$80	\$45			
Other	\$73	\$25	\$28	\$50	\$20	\$22	\$20	\$20			
Drug-Eluting	\$494	\$1,063	\$1,675	\$2,039	\$2,046	\$2,161	\$2,207	\$2,157			
Boston Scientific - Total	\$199	\$574	\$795	\$797	\$704	\$611	\$626	\$596			
Boston Scientific - Promus	\$0	\$0	\$0	\$0	\$112	\$267	\$333	\$351			
Boston Scientific - TAXUS Liberté	\$199	\$574	\$795	\$797	\$592	\$344	\$293	\$245			
Johnson & Johnson	\$276	\$454	\$731	\$722	\$584	\$386	\$305	\$225			
Medtronic	\$0	\$0	\$79	\$270	\$314	\$364	\$372	\$383			
Abbott - Xience	\$0	\$0	\$0	\$40	\$249	\$557	\$638	\$698			
Conor (End-User)	\$0	\$0	\$3	\$65	\$15	\$0	\$0	\$0			
Other	\$19	\$35	\$67	\$145	\$180	\$243	\$266	\$255			
Europe and ROW Stent Market Shares											
Bare Metal	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
Boston Scientific	14%	15%	17%	18%	26%	26%	26%	26%	19%	18%	18%
Guidant	30%	35%	35%	34%	40%	40%	44%	46%	44%	46%	46%
Johnson & Johnson	12%	7%	8%	3%	3%	3%	3%	3%	3%	3%	3%
Medtronic	32%	38%	35%	34%	25%	27%	27%	27%	27%	23%	23%
Other	11%	5%	6%	11%	5%	6%	7%	10%	10%	10%	10%
Drug-Eluting	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
Boston Scientific - Total	40%	54%	47%	39%	34%	28%	28%	28%	28%	28%	28%
Boston Scientific - Promus	0%	0%	0%	0%	5%	12%	15%	16%	16%	16%	16%
Boston Scientific - TAXUS Liberté	40%	54%	47%	39%	29%	16%	13%	11%	11%	11%	11%
Johnson & Johnson	56%	43%	44%	35%	29%	18%	14%	10%	10%	10%	10%
Medtronic	0%	0%	5%	13%	15%	17%	17%	18%	18%	18%	18%
Abbott - Xience	0%	0%	0%	2%	12%	26%	29%	32%	32%	32%	32%
Conor (End-User)	0%	0%	0%	3%	1%	0%	0%	0%	0%	0%	0%
Other	4%	3%	4%	7%	9%	11%	12%	12%	12%	12%	12%

E - Morgan Stanley Research Estimate

Source: Morgan Stanley Research

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May 7, 2007

Hosp Supplies &amp; Medical Technology

**Exhibit 7**  
**Worldwide Quarterly Coronary Stent Sales to End User Customers, 2000-2010E**

*(\$ Millions)*

	Domestic						International						Worldwide					
	JNJ	ABT/GDT	MDT	BSN	Other	Total	JNJ	ABT/GDT	MDT	BSN	Other	Total	JNJ	ABT/GDT	MDT	BSN	Other	Total
<b>2002A</b>																		
1QA	81	147	59	30	10	326	47	61	53	34	13	210	128	210	112	64	23	516
2QA	103	141	52	25	12	333	65	74	46	35	12	232	168	215	98	60	24	563
3QA	99	143	47	36	16	340	83	76	49	32	11	251	182	219	96	68	27	591
4QA	104	145	39	89	15	392	105	85	49	37	11	287	209	230	88	126	26	679
Year	387	576	197	180	52	1392	300	298	197	138	47	980	687	874	394	318	99	2372
<b>03A/02A</b>																		
1QA	-38%	-20%	-44%	147%	-40%	-14%	134%	37%	19%	21%	15%	50%	25%	-3%	-14%	80%	-9%	11%
2QA	118%	-26%	-40%	136%	-83%	25%	54%	34%	17%	83%	100%	47%	93%	-5%	-16%	105%	8%	34%
3QA	139%	-35%	-49%	25%	-94%	76%	6%	23%	23%	181%	164%	44%	187%	-15%	-12%	99%	13%	62%
4QE	352%	-39%	-16%	-61%	-91%	60%	3%	19%	13%	222%	182%	48%	177%	-18%	11%	22%	24%	53%
Year	205%	-30%	-40%	18%	-81%	18%	35%	28%	23%	128%	111%	47%	131%	-10%	-9%	66%	10%	42%
<b>2003A</b>																		
1QA	30	117	13	74	6	280	110	87	61	41	15	316	160	264	96	115	21	596
2QA	225	164	28	59	2	418	100	100	54	64	24	342	125	203	82	123	26	759
3QA	415	91	24	45	1	598	88	94	60	30	29	161	524	187	84	135	10	959
4QA	470	88	15	15	1	627	108	101	65	11	41	424	578	189	98	154	32	1051
Year	1180	402	118	213	10	1923	406	381	242	114	99	1442	1586	781	360	527	109	3365
<b>04A/03A</b>																		
1QA	774%	-39%	-35%	72%	-100%	137%	18%	2%	13%	280%	13%	46%	254%	-23%	3%	146%	-5%	89%
2QA	-4%	-67%	-61%	710%	-100%	77%	50%	-31%	13%	172%	-25%	38%	13%	-49%	-12%	430%	-11%	60%
3QA	37%	-67%	-54%	1042%	-100%	39%	102%	-34%	11%	91%	-48%	37%	-14%	-50%	-7%	408%	-56%	38%
4QA	-34%	-72%	-73%	1366%	-100%	37%	143%	-18%	18%	82%	-61%	49%	-1%	-54%	-12%	374%	-63%	42%
Year	5%	-60%	-50%	660%	-100%	61%	78%	-27%	14%	129%	-34%	43%	24%	-43%	-7%	340%	-40%	51%
<b>2004A</b>																		
1QA	437	72	28	127	0	664	130	85	71	156	20	462	567	157	99	283	20	1126
2QA	216	34	11	478	0	739	150	69	61	174	18	472	366	103	72	652	18	1211
3QA	274	31	11	514	0	830	178	62	67	172	15	494	452	93	78	686	15	1324
4QA	310	25	9	513	0	857	264	62	77	217	12	632	574	87	86	730	12	1489
Year	1237	162	59	1632	0	3090	722	278	276	719	65	2060	1959	440	335	2351	65	5150
<b>05A/04A</b>																		
1QA	27%	-56%	-68%	295%	NM	30%	138%	-32%	3%	40%	10%	48%	13%	-43%	-17%	153%	10%	37%
2QA	48%	-42%	-45%	0%	NM	13%	133%	19%	20%	28%	28%	53%	83%	-17%	10%	7%	28%	29%
3QA	27%	-40%	-45%	-20%	NM	-5%	79%	-23%	25%	29%	67%	41%	47%	-18%	15%	8%	67%	12%
4QA	10%	8%	-11%	-20%	NM	0%	27%	15%	17%	6%	150%	17%	17%	-8%	12%	-12%	150%	2%
Year	7%	-28%	-54%	10%	NM	6%	82%	-23%	16%	21%	94%	38%	15%	25%	4%	15%	54%	19%
<b>2005A</b>																		
1QA	117	12	9	502	0	830	310	58	71	219	22	682	627	90	82	721	22	1542
2QA	120	10	6	470	0	814	149	56	71	222	25	724	669	86	79	700	23	1557
3QA	147	28	6	411	0	792	118	48	84	222	25	697	665	76	80	633	25	1489
4QA	340	27	6	405	0	782	314	53	30	211	10	738	674	80	96	640	10	1520
Year	1324	117	27	1808	0	3268	1341	215	120	894	100	2840	2635	332	347	2694	100	6108
<b>06A/05A</b>																		
1QA	15%	-9%	-13%	-14%	NM	3%	15%	-17%	48%	9%	150%	18%	15%	-14%	39%	7%	150%	6%
2QA	11%	0%	50%	-8%	NM	0%	-3%	-29%	52%	8%	161%	0%	4%	19%	12%	-3%	161%	4%
3QA	-6%	43%	100%	-4%	NM	-2%	-4%	-27%	43%	-5%	180%	6%	-5%	-1%	47%	-4%	180%	2%
4QA	18%	122%	150%	-15%	NM	10%	-9%	51%	43%	-13%	173%	8%	-13%	75%	50%	-14%	173%	-1%
Year	0%	36%	56%	-10%	NM	-1%	0%	-6%	46%	0%	167%	10%	0%	9%	47%	-7%	167%	3%
<b>2006A</b>																		
1QA	366	29	6	430	0	831	356	48	108	238	55	805	722	77	114	668	55	1636
2QA	355	30	9	440	0	834	340	40	111	240	60	791	695	70	120	680	60	1625
3QA	327	40	12	396	0	775	305	35	120	213	70	741	652	75	132	607	70	1516
4QA	280	60	15	347	0	702	305	80	129	203	82	797	585	140	144	548	82	1499
Year	1328	159	42	1613	0	3142	1306	203	468	890	267	3134	2634	362	510	2503	267	6276
<b>07E/06A</b>																		
1QE	-14%	159%	267%	26%	NM	21%	-22%	77%	15%	-12%	51%	1%	28%	108%	28%	-21%	51%	12%
2QE	-32%	117%	122%	-13%	NM	26%	25%	150%	8%	-1%	8%	2%	-20%	NM	17%	-23%	8%	14%
3QE	-32%	86%	108	-27%	NM	-25%	-28%	220%	-4%	40%	-16%	6%	-10%	NM	1%	-4%	-16%	-10%
4QE	-16%	NM	NM	-24%	NM	-12%	33%	88%	-19%	60%	-40%	1%	-34%	NM	68%	7%	-40%	-4%
Year	34%	NM	NM	-28%	NM	-27%	120%	-1%	19%	-12%	1%	-10%	88%	10%	-51%	-12%	-10%	
<b>2007E</b>																		
1QA	230	75	22	317	0	654	278	85	124	210	83	780	518	160	146	527	83	1434
2QA	230	65	20	295	0	620	255	100	120	232	63	722	495	165	140	527	65	1392
3QE	222	55	18	289	0	584	220	112	115	295	45	787	442	167	133	584	45	1371
4QE	180	40	137	264	0	621	204	150	105	322	42	823	384	190	242	586	42	1444
Year	882	255	197	1165	0	2479	957	447	464	1059	235	3162	1839	682	661	2224	235	5641
<b>08E/07E</b>																		
1QE	-44%	214%	90%	28%	NM	-1%	-43%	60%	28%	2%	18%	2%	-43%	113%	47%	-14%	18%	0%
09E/08E	-48%	17%	26%	-16%	NM	0%	-18%	41%	1%	-15%	6%	2%	-33%	39%	11%	-15%	6%	1%
10E/09E	-7%	-2%	13%	0%	NM	1%	-34%	8%	-10%	-7%	17%	-4%	-24%	3%	0%	-4%	17%	-2%
<b>2008E</b>																		
1QA	495	739	375	833	0	2442	549	717	595	1076	278	3215	1044	1436	970	1909	278	5657
2009E	255	1015	473	701	0	2444	449	1013	603	917	296	3228	704	2028	1076	1618	296	5722
2010E	236	995	535	700	0	2466	298	1094	544	851	347	3134	554	2089	1079	1551	347	5600

Source: Morgan Stanley Research

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## Exhibit 8

## Worldwide Quarterly Coronary Stent Market Shares to End User Customers, 2000-2010E

	Domestic						International						Worldwide					
	JNJ	GDT	MDT	BSX	Other	Total	JNJ	GDT	MDT	BSX	Other	Total	JNJ	GDT	MDT	BSX	Other	Total
2000																		
1Q	6%	45%	30%	17%	1%	100%	13%	28%	25%	23%	11%	100%	9%	39%	29%	19%	5%	100%
2Q	7%	44%	27%	21%	1%	100%	13%	29%	26%	23%	9%	100%	9%	39%	27%	21%	4%	100%
3Q	15%	34%	30%	20%	1%	100%	15%	28%	29%	20%	8%	100%	15%	31%	30%	20%	4%	100%
4Q	15%	43%	30%	11%	1%	100%	14%	27%	27%	23%	9%	100%	14%	37%	29%	16%	4%	100%
Year	10%	42%	29%	17%	1%	100%	14%	28%	27%	22%	9%	100%	12%	37%	28%	19%	4%	100%
2001A																		
1Q	15%	41%	28%	14%	1%	100%	16%	26%	29%	21%	8%	100%	16%	36%	28%	17%	4%	100%
2Q	21%	34%	30%	13%	1%	100%	17%	29%	27%	21%	6%	100%	20%	32%	29%	16%	3%	100%
3Q	23%	38%	25%	12%	1%	100%	17%	29%	28%	19%	6%	100%	21%	35%	27%	14%	3%	100%
4Q	26%	48%	14%	11%	1%	100%	26%	28%	23%	17%	5%	100%	26%	40%	18%	13%	3%	100%
Year	21%	40%	25%	13%	1%	100%	19%	28%	27%	19%	6%	100%	21%	36%	25%	15%	3%	100%
2002A																		
1QA	25%	45%	18%	9%	3%	100%	22%	30%	25%	16%	6%	100%	24%	39%	21%	12%	4%	100%
2QA	31%	42%	16%	8%	4%	100%	28%	32%	20%	15%	5%	100%	30%	38%	17%	11%	4%	100%
3QA	29%	42%	14%	11%	5%	100%	33%	30%	20%	13%	4%	100%	31%	37%	16%	12%	4%	100%
4QA	27%	37%	10%	23%	4%	100%	37%	30%	17%	13%	4%	100%	31%	34%	13%	19%	4%	100%
Year	28%	41%	14%	13%	4%	100%	31%	30%	20%	14%	5%	100%	29%	37%	17%	13%	4%	100%
2003A																		
1QA	18%	42%	12%	26%	2%	100%	35%	27%	20%	13%	5%	100%	27%	34%	16%	19%	4%	100%
2QA	54%	25%	7%	14%	0%	100%	29%	29%	16%	19%	7%	100%	43%	27%	11%	16%	3%	100%
3QA	73%	16%	4%	8%	0%	100%	24%	26%	17%	25%	8%	100%	55%	19%	9%	14%	3%	100%
4QA	75%	14%	5%	6%	0%	100%	25%	24%	15%	28%	7%	100%	55%	18%	9%	15%	3%	100%
Year	61%	21%	6%	11%	1%	100%	28%	26%	17%	22%	7%	100%	47%	23%	11%	16%	3%	100%
2004A																		
1QA	66%	11%	4%	19%	0%	100%	28%	18%	15%	34%	4%	100%	50%	14%	9%	25%	2%	100%
2QA	29%	5%	1%	65%	0%	100%	32%	15%	13%	37%	4%	100%	30%	9%	6%	54%	1%	100%
3QA	33%	4%	1%	62%	0%	100%	36%	13%	14%	35%	3%	100%	34%	7%	6%	52%	1%	100%
4QA	36%	3%	1%	60%	0%	100%	42%	10%	12%	34%	2%	100%	39%	6%	6%	49%	1%	100%
Year	40%	5%	2%	53%	0%	100%	35%	13%	13%	35%	3%	100%	38%	9%	7%	46%	1%	100%
2005A																		
1QA	37%	4%	1%	58%	0%	100%	45%	9%	11%	32%	3%	100%	41%	6%	5%	47%	1%	100%
2QA	38%	4%	1%	57%	0%	100%	48%	8%	10%	31%	3%	100%	43%	6%	5%	45%	1%	100%
3QA	44%	4%	1%	52%	0%	100%	46%	7%	12%	32%	4%	100%	45%	5%	6%	43%	2%	100%
4QA	43%	3%	1%	52%	0%	100%	45%	7%	12%	31%	4%	100%	44%	5%	6%	42%	2%	100%
Year	41%	4%	1%	55%	0%	100%	46%	8%	11%	31%	4%	100%	43%	5%	6%	44%	2%	100%
2006A																		
1QA	44%	3%	1%	52%	0%	100%	44%	6%	13%	30%	7%	100%	44%	5%	7%	41%	3%	100%
2QA	43%	4%	1%	53%	0%	100%	43%	5%	14%	30%	8%	100%	43%	4%	7%	42%	4%	100%
3QA	42%	5%	2%	51%	0%	100%	41%	5%	16%	28%	9%	100%	42%	5%	9%	40%	5%	100%
4QA	40%	9%	2%	49%	0%	100%	38%	10%	16%	25%	10%	100%	39%	9%	10%	37%	5%	100%
Year	42%	5%	1%	51%	0%	100%	42%	6%	15%	28%	9%	100%	42%	6%	8%	40%	4%	100%
2007E																		
1QE	37%	11%	3%	48%	0%	100%	36%	11%	16%	27%	11%	100%	36%	11%	10%	37%	6%	100%
2QE	39%	10%	3%	48%	0%	100%	33%	13%	16%	30%	8%	100%	36%	12%	10%	38%	5%	100%
3QE	38%	9%	3%	49%	0%	100%	28%	14%	15%	37%	6%	100%	32%	12%	10%	43%	3%	100%
4QE	29%	6%	22%	43%	0%	100%	25%	18%	13%	39%	5%	100%	27%	13%	17%	41%	3%	100%
Year	36%	9%	8%	47%	0%	100%	30%	14%	15%	33%	7%	100%	33%	12%	12%	39%	4%	100%
2008E	20%	30%	15%	34%	0%	100%	17%	22%	19%	33%	9%	100%	18%	26%	17%	34%	5%	100%
2009E	10%	42%	19%	29%	0%	100%	14%	31%	18%	28%	9%	100%	12%	35%	19%	28%	5%	100%
2010E	10%	40%	22%	28%	0%	100%	10%	35%	17%	27%	11%	100%	10%	37%	19%	28%	6%	100%

E - Morgan Stanley Research Estimates  
Source: Morgan Stanley Research



MORGAN STANLEY RESEARCH

May 7, 2007

Hosp Supplies &amp; Medical Technology

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Unless otherwise stated, the individuals listed on the cover page of this report are research analysts

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### Global Stock Ratings Distribution

(as of April 30, 2007)

# Morgan Stanley

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Stock Rating Category	Coverage Universe		Investment Banking Clients (IBC)		
	Count	% of Total	Count	% of Total % of Rating IBC	Category
Overweight/Buy	850	38%	291	42%	34%
Equal-weight/Hold	1008	45%	303	44%	30%
Underweight/Sell	368	17%	97	14%	26%
<b>Total</b>	<b>2,226</b>		<b>691</b>		

Data include common stock and ADRs currently assigned ratings. An investor's decision to buy or sell a stock should depend on individual circumstances (such as the investor's existing holdings) and other considerations. Investment Banking Clients are companies from whom Morgan Stanley or an affiliate received investment banking compensation in the last 12 months.

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**Overweight (O):** The stock's total return is expected to exceed the average total return of the analyst's industry (or industry team's) coverage universe, on a risk-adjusted basis, over the next 12-18 months.

**Equal-weight (E):** The stock's total return is expected to be in line with the average total return of the analyst's industry (or industry team's) coverage universe, on a risk-adjusted basis, over the next 12-18 months.

**Underweight (U):** The stock's total return is expected to be below the average total return of the analyst's industry (or industry team's) coverage universe, on a risk-adjusted basis, over the next 12-18 months.

**More volatile (V):** We estimate that this stock has more than a 25% chance of a price move (up or down) of more than 25% in a month, based on a quantitative assessment of historical data, or in the analyst's view, it is likely to become materially more volatile over the next 1-12 months compared with the past three years. Stocks with less than one year of trading history are automatically rated as more volatile (unless otherwise noted). We note that securities that we do not currently consider "more volatile" can still perform in that manner.

Unless otherwise specified, the time frame for price targets included in this report is 12 to 18 months.

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**The Americas**

1585 Broadway  
New York, NY 10036-8293  
United States  
Tel: +1 (1) 212 761 4000

**Europe**

25 Cabot Square, Canary Wharf  
London E14 4QA  
United Kingdom  
Tel: +44 (0) 20 7 425 8000

**Japan**

4-20-3 Ebisu, Shibuya-ku  
Tokyo 150-6008  
Japan  
Tel: +81 (0) 3 5424 5000

**Asia/Pacific**

Three Exchange Square  
Central  
Hong Kong  
Tel: +852 2848 5200

**Industry Coverage: Hosp. Supplies & Medical Technology**

Company (Ticker)	Rating (as of)	Price (05/04/2007)
<b>David R. Lewis</b>		
Beckman Coulter (BEC N)	++	\$63 33
CYTYC Corporation (CYTC O)	O (12/20/2006)	\$35 14
Dade Behring (DADE O)	E (12/20/2006)	\$50 76
Foxhollow Technologies (FOXH O)	E (12/20/2006)	\$23 5
Gen-Probe Inc (GPRO O)	O (12/20/2006)	\$52 76
Haemonetics Corporation (HAE N)	E (12/20/2006)	\$49 93
ev3, Inc (EVVV O)	E (12/20/2006)	\$17 9
<b>Matt Miksic</b>		
Biomet (BMET O)	++	\$43 35
Hospira (HSP N)	O (03/01/2007)	\$40 98
Kyphon (KYPH O)	E (12/05/2006)	\$47 99
NuVasive (NUVA O)	O (10/16/2006)	\$26 57
Stryker Corporation (SYK N)	E (10/28/2005)	\$65 86
Zimmer Holdings, Inc (ZMH N)	O (04/28/2006)	\$90 41
<b>Glenn Reicin</b>		
Abbott Laboratories (ABT N)	O (11/15/2006)	\$58 3
Baxter International (BAX N)	O (06/23/2004)	\$57 43
Becton Dickinson (BDX N)	E (06/23/2004)	\$79 78
Boston Scientific (BSX N)	E (09/22/2006)	\$16 16
Edwards Lifesciences (EW N)	U (03/08/2007)	\$48 81
Greatbatch (GB N)	U (08/06/2004)	\$29 44
Hansen Medical, Inc (HNSN O)	O-V (01/03/2007)	\$23 36
Johnson & Johnson (JNJ N)	E (01/30/2006)	\$64 48
Medtronic (MDT N)	E (08/03/2006)	\$53 69
St Jude Medical (STJ N)	O (11/20/2006)	\$44 03

Stock Ratings are subject to change. Please see latest research for each company



# EXHIBIT 22

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF TEXAS  
MARSHALL DIVISION

FILED-CLERK  
U.S. DISTRICT COURT  
2007 MAR 16 PM 1:51  
TX EASTERN-MARSHALL

MEDTRONIC, INC , MEDTRONIC  
USA, INC. , MEDTRONIC VASCULAR  
GALWAY, LTD and EVYSIO  
MEDICAL DEVICES ULC,

Plaintiffs,

v

CORDIS CORPORATION,

Defendant

BY \_\_\_\_\_

Civil Action No. 2 - 07 C V - 088

Jury Trial Demanded

**COMPLAINT**

Plaintiffs Medtronic, Inc , Medtronic, USA, Inc , Medtronic Vascular Galway, Ltd., and Evysio Medical Devices ULC (collectively "Plaintiffs") bring this Complaint against Cordis Corporation ("Defendant") and in support allege as follows:

**JURISDICTION AND VENUE**

1 This is an action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code This Court has federal question jurisdiction pursuant to 28 U S C. § 1331 and exclusive original jurisdiction pursuant to 28 U S C. § 1338(a)

2 Venue is proper in this judicial district pursuant to 28 U S C. §§ 1391(b) and 1400(b)

3 Defendant is subject to personal jurisdiction in this judicial district Defendant has been and is doing business in the State of Texas and is subject to the jurisdiction of this judicial district Defendant has been and is doing business in this judicial district by

manufacturing, distributing, marketing, using, selling and/or offering for sale its products in this judicial district and elsewhere in the United States

**THE PARTIES**

4 Plaintiff Medtronic, Inc (“Medtronic”) is a corporation organized and existing under the laws of the State of Minnesota, with its principal place of business in Minneapolis, Minnesota

5 Plaintiff Medtronic USA, Inc (“Medtronic USA”) is a corporation organized and existing under the laws of the State of Minnesota, with its principal place of business in Minneapolis, Minnesota.

6 Plaintiff Medtronic Vascular Galway, Ltd (“Medtronic Galway”) is a corporation organized and existing under the laws of the Republic of Ireland, with its principal place of business in Galway, Ireland

7 Plaintiff Evysio Medical Devices ULC (“Evysio”) is a corporation organized and existing under the laws of Nova Scotia, Canada, with its principal place of business in Vancouver, British Columbia.

8 On information and belief, Defendant Cordis Corporation is a corporation organized and existing under the laws of the State of Florida, with its principal places of business in Miami Lakes, Florida, and New Brunswick, New Jersey

**COUNT I**

**INFRINGEMENT OF U.S. PATENT NO. 6,881,223 B2**

9. Plaintiffs reallege and incorporate by reference, as if fully set forth herein, all of the allegations contained in paragraphs 1-8 of this complaint.

10. U S Patent No 6,881,223 B2 ("the '223 patent"), entitled "Expandable Stent and Method for Delivery of Same," was duly and legally issued on April 19, 2005, by the U S Patent and Trademark Office to Evysio Medical Devices ULC, the assignee of the named inventors Dr Ian M Penn and Dr Donald R Ricci. A true and correct copy of the '223 patent is attached hereto as Exhibit A.

11. Evysio is the owner of the '223 patent by virtue of an assignment and owns all right and title to the '223 patent, subject to the licenses it has granted.

12. Medtronic is the exclusive licensee of the '223 patent in the field of the human coronary system.

13. Medtronic Galway is the exclusive sublicensee of Medtronic's rights to make and have made outside of the United States, and of its right to import, to use, to sublicense others to use, to offer to sell, to sell, and to exclude others who are unlicensed from importing, using, offering to sell, or selling within the United States, stents, catheters and other products covered by the '223 patent. Some of the accused products are the same products that are at issue in another suit pending in this Court.

14. Medtronic USA is the exclusive sublicensee of Medtronic Galway's rights to use, to sublicense others to use, and to exclude others who are unlicensed from using, within the United States, stents, catheters and other products covered by the '223 patent.

15. Under the terms of their respective license agreements, each of Medtronic, Medtronic Galway, and Medtronic USA has the contractual right to exclude others from practicing the inventions claimed in the '223 patent and to bring this action.

16. Upon information and belief, Defendant has infringed and continues to infringe one or more claims of the '223 patent, directly, contributorily, and/or by inducement, by making,

using, selling and/or offering for sale in this country (and in this judicial district), and inducing others to use, without license, certain stents, including but not limited to all sizes and models of the Cordis Bx VELOCITY® stent and the Cordis CYPHER® stent, in violation of 35 U.S.C. § 271, as well as catheters used with those stents. Some of the accused products are the same products that are at issue in another suit pending in this Court in *Medtronic AVE, Inc. v. Cordis*, 2:03-cv-212-TJW.

17 Defendant has had actual or constructive knowledge of the '223 patent at least as early as 2005, and Defendant's infringement has been willful and deliberate.

18 Plaintiffs have been and will continue to be damaged by Defendant's infringement and will be irreparably harmed unless that infringement is enjoined.

## **COUNT II**

### **INFRINGEMENT OF U.S. PATENT NO. 6,887,264 B2**

19 Plaintiffs reallege and incorporate by reference, as if fully set forth herein, all of the allegations contained in paragraphs 1-18 of this complaint.

20 U.S. Patent No. 6,887,264 B2 ("the '264 patent"), entitled "Expandable Stent and Method for Delivery of Same," was duly and legally issued on May 3, 2005, by the U.S. Patent and Trademark Office to Evysio Medical Devices ULC, the assignee of the named inventors Dr. Ian M. Penn and Dr. Donald R. Ricci. A true and correct copy of the '264 patent is attached hereto as Exhibit B.

21 Evysio is the owner of the '264 patent by virtue of an assignment and owns all right and title to the '264 patent, subject to the licenses it has granted.

22 Medtronic is the exclusive licensee of the '264 patent in the field of the human coronary system.

23 Medtronic Galway is the exclusive sublicensee of Medtronic's rights to make and have made outside of the United States, and of its right to import, to use, to sublicense others to use, to offer to sell, to sell, and to exclude others who are unlicensed from importing, using, offering to sell, or selling within the United States, stents catheters and other products covered by the '264 patent.

24 Medtronic USA is the exclusive sublicensee of Medtronic Galway's rights to use, to sublicense others to use, and to exclude others who are unlicensed from using, within the United States, stents, catheters and other products covered by the '264 patent.

25 Under the terms of their respective license agreements, each of Medtronic, Medtronic Galway, and Medtronic USA has the contractual right to exclude others from practicing the inventions claimed in the '264 patent and to bring this action

26 Upon information and belief, Defendant has infringed and continues to infringe one or more claims of the '264 patent, directly, contributorily, and/or by inducement, by making, using, selling and/or offering for sale in this country (and in this judicial district), and inducing others to use, without license, certain stents, including but not limited to all sizes and models of the Cordis Bx VELOCITY® stent and the Cordis CYPHER® stent, in violation of 35 U S C § 271, as well as catheters used with those stents. Some of the accused products are the same products that are at issue in another suit pending in this Court in Medtronic AVE, Inc v Cordis, 2:03-cv-212 TJW.

27 Defendant has had actual or constructive knowledge of the '264 patent since at least as early as 2005, and Defendant's infringement has been willful and deliberate

28 Plaintiffs have been and will continue to be damaged by Defendant's infringement and will be irreparably harmed unless that infringement is enjoined.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs respectfully request the following:

- A A judgment that Defendant has infringed U S Patent Nos 6,881,223 B2 and 6,887,264 B2;
- B A permanent injunction pursuant to 35 U S C § 283, restraining and enjoining Defendant and their officers, agents, attorneys, employees, and those acting in privity or active concert with them, from infringement of U S Patent Nos 6,881,223 B2 and 6,887,264 B2 for the full terms thereof;
- C An award of damages to Plaintiffs including pre-judgment and post-judgment interest, in an amount adequate to compensate for Defendant's infringement of U S Patent Nos 6,881,223 B2 and 6,887,264 B2;
- D An award of treble damages pursuant to 35 U S C § 284 for willful infringement;
- E An award of Plaintiffs costs and reasonable attorney's fees;
- F A declaration that this case exceptional pursuant to 35 U S C § 285; and,
- G Such other and further relief as this Court deems just and proper.

**JURY DEMAND**

Plaintiffs request a trial by jury on all issues triable by a jury

DATE: March 16, 2007

Respectfully submitted,

BY: Sam Baxter

Samuel F. Baxter, Lead Attorney  
State Bar No 01938000  
Mark L Mathie  
State Bar No 13191550  
Theodore Stevenson III  
State Bar No 19196650  
McKOOL SMITH P C  
P.O. Box O  
Marshall, Texas 75671  
Telephone: (903) 927-2111  
Facsimile: (903) 927-2622

ATTORNEYS FOR PLAINTIFFS

Of Counsel

FOLEY & LARDNER LLP  
Richard S Florsheim  
777 E Wisconsin Avenue  
Milwaukee, WI 53202  
Telephone: (414) 297-5515  
Facsimile: (414) 297-4900

ATTORNEYS FOR PLAINTIFFS

Medtronic, Inc , Medtronic, USA, Inc ,  
Medtronic Vascular Galway, Ltd

Timothy J Vezeau  
Justin L Krieger  
Michael A Dorfman  
KATTEN MUCHIN ROSENMAN LLP  
525 West Monroe Street  
Suite 1900  
Chicago, Illinois 60661-3693  
Telephone: (312) 902-5200  
Facsimile: (312) 902-1061

ATTORNEYS FOR PLAINTIFFS

Evysio Medical Devices ULC



# EXHIBIT 23

REDACTED